IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Wood, Lowell L. Jr.
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Examiner	:	Victoria Campbell
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Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANT'S SUPERSEDING APPEAL BRIEF IN RESPONSE TO NOTICE OF NON-COMPLIANT APPEAL BRIEF DATED 4/28/10

Dear Sir or Madam:

This paper is responsive to the Advisory Action mailed on January 5, 2010, and to the underlying Final Office Action dated October 14, 2009.

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I. REAL PARTY IN INTEREST

The real party in interest on this appeal is Searete, LLC by virtue of assignments of the inventors recorded at reel/frame 015245/0624 on April 19, 2004. Searete, LLC is wholly owned by Intellectual Ventures Management LLC.

II. RELATED APPEALS AND INTERFERENCES

Appellant's legal representative and the real party in interest are unaware of any appeal or interference which will directly affect, be directly affected by, or have a bearing on the Board's decision in the present appeal.

III. STATUS OF CLAIMS

Claims 1-34 and 66-68 are pending. Claims 35-65 have been withdrawn.

The drawings stand objected under 37 CFR §1.121(d). *Office Action*, p. 2 (14 Oct 2009).

The specification stands objected for containing an embedded hyperlink and/or other form of browser-executable code. *Office Action*, p. 2 (14 Oct 2009).

Claims 1-9, 15-17, 20, 21, 25-34, and 66-68 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Publication 2002/0065509 ("Lebel") in view of U.S. Publication 2005/0004553 ("Douk"). *Office Action*, p. 4 (14 Oct 2009).

Claims 1-9, 15-17, 20, 21, 25-34, and 66-68 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 4,944,659 ("Labbe") in view of U.S. Publication 2005/0004553 ("Douk"). *Office Action*, p. 6 (14 Oct 2009).

Claims 1, 10-16, 18, 19, 23, 24, and 66-68 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,296,638 ("Davison") in view of U.S. Publication 2005/0004553 ("Douk"). *Office Action*, p. 8 (14 Oct 2009).

Claims 1 and 22 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,086,528 ("Adair") in view of U.S. Publication 2005/0004553 ("Douk"). *Office Action*, p. 9 (14 Oct 2009).

Appellant appeals the rejections of Claims 1-9, 15-17, 20, 21, 25-34, and 66-68 under 35 U.S.C. §103(a); the rejections of Claims 1-9, 15-17, 20, 21, 25-34, and 66-68 under 35 U.S.C. §103(a); the rejections of Claims 1, 10-16, 18, 19, 23, 24, and 66-68 under 35 U.S.C. §103(a); and the rejections of Claims 1 and 22 under 35 U.S.C. §103(a).

All pending claims are attached as Appendix A.

IV. STATUS OF AMENDMENTS

An Amendment under 37 C.F.R. 1.116 filed 09 December 2009 in response to the Examiner's Final Office Action dated 14 October 2009 has been refused entry by Examiner Campbell. Appellant's amendments to the drawings and the specification appear also to have been refused entry by Examiner Campbell.

V. SUMMARY OF CLAIMED SUBJECT MATTER

USPTO rejections of one set of claims[1] is appealed herein: (i) Independent Claim 1 and its Dependent Claims 2-34 and 66-68.

A. Summary of Independent Claim 1 and its Dependent Claims 2-34 and 66-68

Support for these claims appears throughout Appellant's application.

In one instance, a device for perfusion management includes, but is not limited to, a body portion; at least one extensible finger coupled to said body portion, the extensible finger being composed of a plurality of retractable segments, the plurality of retractable segments of the extensible finger configured to controllably telescopically extend from the body portion; at least one reservoir in communication with said extensible finger; and a control circuitry coupled to said extensible finger, and/or said body portion. *See application at, e.g. page 2, Line 1 and page 6, line 15 (Independent Claim 1).*

In another instance, the device for perfusion management further includes, but is not limited to, a device for data gathering, data processing, data storage, and/or data transmission. *See application at, e.g. page 7, line 30 (Dependent Claim 2).*

In another instance, the device for perfusion management further includes, but is not limited to, an imager, a pressure sensor, a temperature sensor, a chemical sensor, a gas sensor, an electrolyte sensor, a composition sensor, a concentration sensor, and/or a flow sensor coupled to said extensible finger. *See application at, e.g. page 6, line 10 and Page 9, Line 1 (Dependent Claim 3).*

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[1] Appellant respectfully points out that in accordance with 37 CFR §41.37(c)(1)(v), Appellant herein provides a "summary of claimed subject matter [having a] concise explanation of the subject matter defined in each of the independent claims involved in the appeal, which shall refer to the specification by page and line number, and to the drawing, if any, by reference characters. For each independent claim involved in the appeal and for each dependent claim argued separately under the provisions of paragraph (c)(1)(vii) of this section, every means plus function and step plus function as permitted by 35 U.S.C. §112, sixth paragraph, must be identified and the structure, material, or acts described in the specification as corresponding to each claimed function must be set forth with reference to the specification by page and line number, and to the drawing, if any, by reference characters." However, Appellant respectfully points out that the herein-provided summary is illustrative only and is NOT intended to be in any way limiting. Appellant is providing this summary under protest that the USPTO's regulations in this area exceed its statutory authority (*e.g.* are *ultra vires*).

In another instance, the device for perfusion management further includes, but is not limited to, a pump, and/or a source of pressure coupled to said extensible finger. *See application at, e.g. page 5, line 30 (Dependent Claim 4).*

In another instance, the device for perfusion management further includes, but is not limited to, a motor and/or an actuator coupled to said extensible finger. See application *at, e.g. page 8, line 25 (Dependent Claim 5).*

In another instance, the device for perfusion management further includes, but is not limited to, a wireless data transmitter, coupled to said extensible finger and/or said control circuitry. *See application at, e.g. page 7, line 30 (Dependent Claim 6).*

In another instance, the device for perfusion management further includes, but is not limited to, a wireless data receiver, and/or a wireless data controller coupled to said extensible finger and/or said control circuit. *See application at, e.g. page 7, line 30 (Dependent Claim 7).*

In another instance, the device for perfusion management includes, but is not limited to, wherein said at least one extensible finger is coupled to a source of a chemical, a chemical compound, a protein, a lipoprotein, a glycoprotein, a sugar, a lipid, an antigen, an antibody, a cytokine, a peptide, a neurotransmitter, a hormone, an ion, a messenger molecule, a nucleic acid, an engineered nucleic acid, a nucleic acid vector, a drug, a cell, a cell fragment, a cell organelle, a liposome, a pharmaceutical agent, a biological material, and/or a biological fraction internal and/or external to said reservoir. *See application at, e.g. page 5, line 1 (Dependent Claim 8).*

In another instance, the device for perfusion management includes, but is not limited to, wherein said at least one extensible finger is coupled to a source of two or more of a chemical, a chemical compound, a protein, a lipoprotein, a glycoprotein, a sugar, a lipid, an antigen, an antibody, a cytokine, a peptide, a neurotransmitter, a hormone, an ion, a messenger molecule, a nucleic acid, an engineered nucleic acid, a nucleic acid vector, a drug, a cell, a cell fragment, a cell organelle, a liposome, a pharmaceutical agent, a biological material, and/or a biological fraction internal and/or external to said reservoir. *See application at, e.g. page 5, line 1 (Dependent Claim 9).*

In another instance, the device for perfusion management further includes, but is not limited to, an operative tool in communication with said extensible finger. *See application at, e.g. page 7, line 1 (Dependent Claim 10).*

In another instance, the device for perfusion management includes, but is not limited to, wherein said operative tool comprises a tool positioner. *See application at, e.g. page 7, line 1 (Dependent Claim 11).*

In another instance, the device for perfusion management includes, but is not limited to, wherein said operative tool comprises a device for ablating and/or degrading and/or liquefying a cell, a mass of cells, a tissue, and/or an assembly of biological materials exhibiting shear strength. *See application at, e.g. page 7, line 1 (Dependent Claim 12).*

In another instance, the device for perfusion management includes, but is not limited to, wherein said control circuitry is operative to guide said operative tool. *See application at, e.g. page 7, line 25 (Dependent Claim 13).*

In another instance, the device for perfusion management includes, but is not limited to, wherein said extensible finger includes a source of an electric charge and/or electromagnetic radiation coupled and/or carried by said extensible finger. *See application at, e.g. page 7, line 1 (Dependent Claim 14).*

In another instance, the device for perfusion management includes, but is not limited to, wherein the plurality of retractable segments are configured to articulate at joints of adjacent segments. *See application at, e.g. page 10, line 10 (Dependent Claim 15).*

In another instance, the device for perfusion management includes, but is not limited to, wherein said plurality of retractable segments are hollow. *See application at, e.g. page 7, line 25 (Dependent Claim 16).*

In another instance, the device for perfusion management includes, but is not limited to, wherein said extensible finger further comprises a device for fully or partially blocking and/or shunting a liquid flow. *See application at, e.g. page 5, line 30 (Dependent Claim 17).*

In another instance, the device for perfusion management further includes, but is not limited to, a device for evacuating a target coupled to said extensible finger. *See application at, e.g. page 7, line 1 (Dependent Claim 18).*

In another instance, the device for perfusion management further includes, but is not limited to, a device for cauterizing and/or sealing a cell, a mass of cells, a tissue, and/or an assembly of biological materials exhibiting shear strength carried by said extensible finger. *See application at, e.g. page 7, line 1 (Dependent Claim 19).*

In another instance, the device for perfusion management further includes, but is not limited to, a fluid dispenser operative to provide a fluid at a controlled rate. *See application at, e.g. page 7, line 1 (Dependent Claim 20).*

In another instance, the device for perfusion management includes, but is not limited to, wherein said fluid dispenser is carried by said extensible finger. *See application at, e.g. page 7, line 1 (Dependent Claim 21).*

In another instance, the device for perfusion management includes, but is not limited to, wherein said extensible finger comprises a stent. *See application at, e.g. page 7, line 1 (Dependent Claim 22).*

In another instance, the device for perfusion management includes, but is not limited to, wherein said control circuitry is coupled to control said extensible finger. *See application at, e.g. page 4, line 15 (Dependent Claim 23).*

In another instance, the device for perfusion management includes, but is not limited to, wherein said control circuitry is operative to guide said extensible finger. *See application at, e.g. page 7, line 25 (Dependent Claim 24).*

In another instance, the device for perfusion management includes, but is not limited to, wherein said control circuitry comprises a processor, a feedback circuit, and/or a logic circuit. *See application at, e.g. page 7, line 30 (Dependent Claim 25).*

In another instance, the device for perfusion management includes, but is not limited to, wherein said control circuitry is a processor further comprising a stored software and/or firmware program cooperative with said processor. See application *at, e.g. page 7, line 30 (Dependent Claim 26).*

In another instance, the device for perfusion management includes, but is not limited to, wherein said device is of a size, a composition, a power dissipation level, and/or a shape

configured for full or partial placement in vivo. *See application at, e.g. page 12, line 1 (Dependent Claim 27).*

In another instance, the device for perfusion management includes, but is not limited to, wherein said device is configured for implantation in an animal. *See application at, e.g. page 12, line 1 (Dependent Claim 28).*

In another instance, the device for perfusion management includes, but is not limited to, wherein said animal is human. *See application at, e.g. page 9, line 15 (Dependent Claim 29).*

In another instance, the device for perfusion management includes, but is not limited to, wherein said device is configured for placement in a selected location in said human corresponding to at least one physiological variable to be monitored and/or treated. *See application at, e.g. page 6, line 10 (Dependent Claim 30).*

In another instance, the device for perfusion management includes, but is not limited to, wherein said selected location is in a circulatory system, an aorta and/or a vena cava. *See application at, e.g. page 5, line 20 (Dependent Claim 31).*

In another instance, the device for perfusion management includes, but is not limited to, wherein said device is operative to provide and/or monitor a treatment and/or a response in a patient. *See application at, e.g. page 12, line 10 (Dependent Claim 32).*

In another instance, the device for perfusion management includes, but is not limited to, wherein said treatment comprises delivering a medicinal agent, a pharmaceutical agent, a therapeutic device and/or assembly to a location in said patient. *See application at, e.g. page 5, line 1 (Dependent Claim 33).*

In another instance, the device for perfusion management includes, but is not limited to, wherein said device communicates exterior to said patient. *See application at, e.g. page 7, line 30 (Dependent Claim 34).*

In another instance, the device for perfusion management includes, but is not limited to, wherein the plurality of retractable segments are configured to slidably collapse against adjacent segments and/or within an interior of adjacent segments of larger diameter. *See application at, e.g. page 6, line 10 (Dependent Claim 66).*

In another instance, the device for perfusion management includes, but is not limited to, wherein a length of the at least one extensible finger is controllably adjustable. *See application at, e.g. page 6, line 10 (Dependent Claim 67).*

In another instance, the device for perfusion management includes, but is not limited to, wherein articulation of the at least one extensible finger is controllably adjustable. *See application at, e.g. page 10, line 10 (Dependent Claim 68).*

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues in this response relate to whether the USPTO has met its burden of establishing a *prima facie* case sufficient to establish that Appellant's Claims 1-34 and 66-68 are unpatentable. Specifically, the issues are as follows:

1. Whether the USPTO has met its burden to show that the drawings fail to comply with 37 CFR §1.121(d).

2. Whether the USPTO has met its burden to show that the specification fails to comply with MPEP 608.01.

3. Whether the USPTO has met its burden to show that Claims 1-9, 15-17, 20, 21, 25-34, and 66-68 are unpatentable over U.S. Publication 2002/0065509 ("Lebel") in view of U.S. Publication 2005/0004553 ("Douk").

4. Whether the USPTO has met its burden to show that Claims 1-9, 15-17, 20, 21, 25-34, and 66-68 are unpatentable over U.S. Patent 4,944,659 ("Labbe") in view of U.S. Publication 2005/0004553 ("Douk").

5. Whether the USPTO has met its burden to show that Claims 1, 10-16, 18, 19, 23, 24, and 66-68 are unpatentable over U.S. Patent 6,296,638 ("Davison") in view of U.S. Publication 2005/0004553 ("Douk").

6. Whether the USPTO has met its burden to show that Claims 1 and 22 are unpatentable over U.S. Patent 6,086,528 ("Adair") in view of U.S. Publication 2005/0004553 ("Douk").

VII. ARGUMENT: THE USPTO HAS FAILED TO ESTABLISH A PRIMA FACIE CASE THAT THE DRAWINGS FAIL TO COMPLY WITH 37 CFR 1.121(d)

The drawings stand objected under 37 CFR §1.121(d). *See Office Action*, p. 2 (14 Oct 2009). According to the USPTO, the previously-submitted drawings are "elementary in nature," "not sufficient to describe the invention," and "Figure 3 appears to be comprised of 3 separate figures, none of which is currently labeled independently (i.e.: 3A, 3B, and 3C)."

As an initial matter, the MPEP states as follows: "the examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant. . . If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent." *MPEP* § 2107 (emphasis added) (citing *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992)); *In Re Glaug* 283 F.3d 1335, 62 USPQ2d 1151 (Fed. Cir. 2002); *In re Piasecki*, 745 F.2d 1468, 1472, 223 U.S.P.Q. 785, 788 (Fed. Cir. 1984). ("If the PTO fails to meet this burden, then the applicant is entitled to the patent."). Accordingly, unless and until the USPTO presents evidence establishing a *prima facie* case of the alleged failure of the drawings to comply with 37 CFR 1.121(d), the burden does not shift to Appellant, and Appellant is entitled to a patent on all claims presented for examination. This initial burden is a cornerstone of examination principles and, as such, the Board ensures on appeal that a *prima facie* case for the unpatentability Appellant's claims has been established *without any deference to the USPTO*. *Ex Parte Frye*, Appeal 2009-006013, pp. 9-10 (BPAI 2010) ("an applicant can overcome a rejection by showing insufficient evidence of *prima facie* [unpatentability] ... the Board reviews the particular finding(s) contested by an appellant *anew*.") (emphasis added). Appellant respectfully submits that the USPTO has not met its burden in this regard.

Assuming *arguendo*, and without waiving its assertion that the USPTO has not yet met its burden of proof, Appellant respectfully submits that Appellant has reviewed 37 CFR § 1.84 entitled "Standards for drawings." Appellant can find no requirement that formal drawings be non-"elementary." In fact, legibility and suitability for reproduction appear to be the cornerstone

requirements of 37 CFR § 1.84. Therefore, Appellant respectfully traverses the USPTO's objections to the drawings as being "elementary in nature."

Similarly, Appellant respectfully traverses the Examiner's objections to the drawings as being "not sufficient to describe the invention." The Patent Office and/or the Examiner has conducted examination of the subject application since at least July 11, 2007, and while Appellant and the USPTO have not yet agreed on the proper scope of allowable subject matter, this disagreement does not in any way appear to be attributable to the USPTO's inability to understand the claims or specification of the subject application due to any deficiency of the drawings, but rather, are based on disagreements pertaining to the relevant teachings of the prior art. For the foregoing reasons, Appellant respectfully traverses the USPTO's objections to the drawings as being "not sufficient to describe the invention."

Furthermore, in partial satisfaction of the USPTO's continued requirement for replacement formal drawings, Appellant submitted Replacement Formal Drawings, which appear to have been refused entry. Appellant addressed the USPTO's concern that "Figure 3 appears to be comprised of 3 separate figures, none of which is currently labeled independently (i.e.: 3A, 3B, and 3C)" by independently labeling the three sub-figures shown on Sheet 3. No new matter was added.

Accordingly, Appellant respectfully requests that the Board order entrance of Appellant's drawing amendments and reverse the USPTO's objections to the drawings.

VIII. ARGUMENT: THE USPTO HAS FAILED TO ESTABLISH A PRIMA FACIE CASE THAT THE SPECIFICATION FAILS TO COMPLY WITH MPEP 608.01

The specification stands objected under MPEP §608.01 as containing an embedded hyperlink. *Office Action*, p. 2 (14 Oct 2009). Without waiving any right to contest this objection, Appellant attempted to satisfy the USPTO's objections to the specification by amending the specification to remove the above referenced hyperlink. This amendment appears to have been refused entry.

Accordingly, Appellant respectfully requests that the Board order entrance of Appellant's specification amendments and reverse the USPTO's objections to the specification.

IX. ARGUMENT: ART OF RECORD DOES NOT ESTABLISH *PRIMA FACIE* CASE OF UNPATENTABILITY IN VIEW OF CITED ART OF RECORD

The USPTO has stated that Claims 1-9, 15-17, 20, 21, 25-34, and 66-68 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Publication 2002/0065509 ("Lebel") in view of U.S. Publication 2005/0004553 ("Douk"). *Office Action*, p. 4 (14 Oct 2009). The USPTO has further stated that Claims 1-9, 15-17, 20, 21, 25-34, and 66-68 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 4,944,659 ("Labbe") in view of U.S. Publication 2005/0004553 ("Douk"). *Office Action*, p. 6 (14 Oct 2009). The USPTO has further stated that Claims 1, 10-16, 18, 19, 23, 24, and 66-68 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,296,638 ("Davison") in view of U.S. Publication 2005/0004553 ("Douk"). *Office Action*, p. 8 (14 Oct 2009). The USPTO has further stated that Claims 1 and 22 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,086,528 ("Adair") in view of U.S. Publication 2005/0004553 ("Douk"). *Office Action*, p. 9 (14 Oct 2009).

In response, Appellant respectfully asserts herein that, under the MPEP and legal standards for patentability as set forth below, the art of record does not establish a *prima facie* case of the unpatentability of Appellant's claims at issue. Specifically, Appellant respectfully shows below that the art of record does not recite or suggest the text of Appellant's claims at issue, and hence fails to establish a *prima facie* case of unpatentability. Accordingly, Appellant respectfully requests that the Board reverse the Examiner's rejections and hold all claims to be allowable over the art of record.

A. Legal Standards for Patentability

The MPEP states as follows: "the examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant. . . If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent." *MPEP* § 2107 (citing *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992)); *In Re Glaug*, 283 F.3d 1335,

62 USPQ2d 1151 (Fed. Cir. 2002) ("During patent examination the PTO bears the initial burden of presenting a *prima facie* case of unpatentability. *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 U.S.P.Q. 785, 788 (Fed. Cir. 1984). If the PTO fails to meet this burden, then the applicant is entitled to the patent."). Accordingly, unless and until an examiner presents evidence establishing *prima facie* unpatentability, an applicant is entitled to a patent on all claims presented for examination. This initial burden is a cornerstone of examination principles and, as such, the Board ensures on appeal that a *prima facie* case for the unpatentability Applicant's claims has been established *without any deference to the USPTO*. *Ex Parte Frye*, Appeal 2009-006013, pp. 9-10 (BPAI 2010) ("an applicant can overcome a rejection by showing insufficient evidence of *prima facie* [unpatentability] ... the Board reviews the particular finding(s) contested by an appellant *anew*.") (emphasis added).

For example, in making an obviousness rejection, the evidence required must come in the form of particular findings: "[b]road conclusory statements standing alone are not 'evidence'." *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000) (citing In re Dembiczak, 175 F.3d 994, 999 (Fed. Cir. 1999)). The Supreme Court has affirmed this requirement in its *KSR v. Teleflex* decision: "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR v. Teleflex, 550 U.S. 398; 127 S. Ct. 1727 at 1741* (citing *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006)).

The court in *Kotzab* held that "more than a mere scintilla of evidence is necessary" to support an Examiner's *prima facie* case. In re Kotzab, 217 F.3d 1365, 1371 (Fed. Cir. 2000). This underscores the requirement for *some* evidence in making a prima facie case; rejections based on *no* evidence have repeatedly been reversed by the Federal Circuit. See *In re McNeil-PPC*, 2008-1546, slip op. 1, 10 (Fed. Cir. July 31, 2009) (anticipation rejection reversed where findings by the BPAI about the disclosures of a prior art patent application are not supported by substantial evidence), *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000) (obviousness rejection reversed where there was no finding as to the specific understanding or principle needed to support Examiner's prima facie case), and *In re Robert Skvorecz*, 2008-1221, slip op. 1, 7 (Fed.

Cir. September 3, 2009) (anticipation rejection reversed where Examiner's assertion that reference contained identical recitations as the claim was unsupported by any evidence).

1. What a Reference "Teaches" Is a Question of Fact

What a reference "teaches" is a question of fact.[2,3,4] Conclusory statements that a reference "teaches" something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such "teachings" unless they are supported by objective evidence of record. *See In re McNeil-PPC,* 2008-1546 (Fed. Cir. July 31, 2009);[5] *In re Lee,* 277 F.3d 1338 (Fed. Cir. 2002);[6] *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000) ("Whether the Board relies on an

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[2] *See Rapoport v. Dement,* 254 F.3d 1053, 1060 (Fed. Cir. 2001) ("What a reference **teaches** is a question of fact,.. Therefore, we review the Board's **characterization** of the **disclosure** in the FPR Publication for **substantial evidence**.") (emphasis added).

[3] *In re Bell***,** 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO and holding when the PTO presented no evidence to cure *prima facie* differences between patent claim and Examiner assertions regarding what the allegedly invalidating prior art "taught")

[4] Anticipation**,** as well as what a reference teaches**,** is a question of fact. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002).

[5] In *McNeil,* the Examiner had rejected claims reciting a tampon having "a generally cylindrical compressed, solid fibre core" and ribs "compressed less than the fiber core" in view of a Japanese patent application ("Sasaki"). McNeil appealed to the Board of Patent Appeals and Interferences, which "specifically found that 'Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward.' " *See id.,* 2008-1546, slip op. 1, 3 (Fed. Cir. July 31, 2009). In light of this and its finding that of each rib of Sasaki being "compressed less than the fiber core," the Board affirmed the rejections. Insofar that the Sasaki reference did not directly disclose/recite as alleged by the Board, and since the Board did not supply evidence supporting its statement that "Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward," the Federal Circuit reversed the rejection for lack of "substantial evidentiary support," stating as follows:

> There is not substantial evidence, indeed, no evidence, that Sasaki discloses ribs "compressed less than the fiber core" or "a generally cylindrical compressed, solid fibre core." ... Just as the Sasaki figures do not indicate the relative compression of the different portions of the tampon, the Sasaki figures completely lack any indication of the relative coarseness of different portions. ... Lastly, turning to the issue of spacing of the ribs, Figure 8 shows a space between the bottommost ribs, and there is arguably some space shown between other ribs. However, because it is neither clear that Sasaki discloses a core nor which portions of Sasaki's tampon the Board considered to be the ribs and which the Board considered to be the core, we cannot say that substantial evidence supports the Board's determination that Sasaki discloses ribs separated from each other "at the proximal end by an amount greater than" than at "the distal end."

See id., 2008-1546, slip op. 1, 10-11 (Fed. Cir. July 31, 2009).

[6] In *Lee,* the USPTO argued that, to the "common sense of a person of ordinary skill in the art," it was obvious that one could combine a prior patent for an on-screen television menu with an on-screen picture-quality adjustment for a

express or an implicit showing, it must provide particular findings related thereto. … Broad conclusory statements standing alone are not "evidence.").[7] Even if the PTO personnel were to seek to support their characterizations with an expert witness affidavit, the law is that conclusory statements by an expert that a reference "teaches" something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such "teachings" unless they are supported by objective documentary evidence.[8] Thus, when a party to a matter asserts that a reference "teaches" something beyond its bare recitations/direct disclosure, and that factual assertion is

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video game played on a television illustrated in the game's handbook. The Federal Circuit ruled that obviousness must be based on "objective evidence of record." Finding no specific published suggestion in the record, the Federal Circuit ruled the invention patentable. *See id.,* 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (describing the BPAI's obligation to develop an evidentiary basis for its factual findings to allow for meaningful judicial review under the substantial evidence standard).

[7] In *Kotzab*, the Federal Circuit reversed the BPAI as follows:

> The Examiner cites Evans for teaching that "one *system* constructed and operated according to the invention may be used to control a number of valves." Evans application, p. 19, ll. 6-8 (emphasis added). In view of this disclosure only, the Examiner concluded that Evans teaches the use of one *sensor* to control a number of valves. This conclusion must necessarily rest on the unstated premise by the Examiner that "one system" is equal to "one sensor."
>
> But the Board's decision, adopting the Examiner's premise, lacks the necessary substantial evidence to support a rejection of Kotzab's claims. Specifically, there is not substantial evidence to show that "one system" is the same thing as "one sensor." The words "sensor" and "probe" are used throughout Evans to refer to the device that measures the mold temperature. … Evans clearly never uses the term "system" as a substitute for the simple temperature measuring device it calls "sensor." And, the Board made no reference to any evidence in the record that would equate "one system" with "one sensor."
>
> As mentioned previously, more than a mere scintilla of evidence is necessary to support the Board's implicit conclusion that "one system" is equal to "one sensor." Based on the entirety of Evans' disclosure, we cannot say that there is such relevant evidence as a reasonable mind might accept as adequate to support the conclusion that "one system" means "one sensor."

See id., 217 F.3d 1365, 1370-71 (Fed. Cir. 2000) (underline added).

[8] *See Motorola, Inc. v. Interdigital Tech. Corp.,* 121 F.3d 1461, 1473 (Fed. Cir. 1997) ("The district court's holding misapprehends the rigors of anticipation. For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art... **Although this disclosure requirement presupposes the knowledge of one skilled in the art of the claimed invention, that presumed knowledge does not grant a license to read into the prior art reference teachings that are not there. An expert's conclusory testimony, unsupported by the documentary evidence, cannot supplant the requirement of anticipatory disclosure in the prior art reference itself.**") (emphasis added); *see also Genzyme Corp. v. Atrium Med. Corp.,* 315 F. Supp. 2d 552, 563 (D. Del. 2004) ("For a patent to be anticipated, every element of a patent claim must appear in a single reference. **Other references and opinion may be used to reveal what the reference would have meant to those skilled in the art at the time of the invention.... For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art. Presumed knowledge of one skilled in the art does not allow an expert to read into the reference elements that are not there.**") (emphasis added)

challenged by an opposite party, the law requires that the asserting party provide objective evidentiary support to "close the gap" between what the reference recites and the what the asserting party *alleges* the reference teaches; in the absence of such evidence, there should be no finding of fact in favor of the asserted teaching.[9,10,11,12,13]

2. MPEP Standards for Determining Anticipation

An examiner bears the initial burden of factually supporting any *prima facie* conclusion of anticipation. *Ex Parte Skinner*, 2 U.S.P.Q.2d 1788, 1788-89 (B.P.A.I. 1986); *In Re King, 801 F.2d 1324, 231 U.S.P.Q. (BNA) 136 (Fed. Cir. 1986); MPEP* § 2107 (citing *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992) ("[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability....")). Failure of an examiner to meet this burden entitles an applicant to a patent. *Id*. ("[i]f examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent"). This initial burden is a cornerstone of examination principles and, as such, the Board ensures on appeal that a *prima*

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[9] *See Rapoport v. Dement*, 254 F.3rd 1053, 1060 (Fed. Cir. 2001) . In *Rapoport,* the Federal Circuit affirmed the Board's holding that a publication did not anticipate a claim, reasoning as follows (emphasis added):

> Having construed the disputed term in the interference count and affirmed the Board's interpretation, we can properly address the merits of Rapoport's anticipation argument. The Board found that the disclosure of the FPR Publication was limited to treatment of anxiety in patients suffering from sleep apnea with buspirone, and did not address treatment of the underlying sleep apnea disorder. What a reference **teaches** is a question of fact.... There is no disclosure in the FPR Publication of tests in which buspirone is administered to patients suffering from sleep apnea with the intent to cure the underlying condition.... The Board also correctly found that the FPR Publication does not show administering buspirone in any specific amounts to patients suffering from sleep apnea.... We note that there is no mention in the FRP Publication of administering buspirone to a patient at bedtime.... Therefore, for all the reasons stated above, we find that the Board's conclusion that the FPR Publication does not disclose administration of buspirone to patients suffering from sleep apnea to treat sleep apnea is supported by substantial evidence.

[10] *See In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing PTO and holding, when PTO presented no evidence to cure *prima facie* differences between patent claim and Examiner assertions regarding what the allegedly invalidating prior art "taught").

[11] *See In re McNeil-PPC,* 2008-1546 (Fed. Cir. July 31, 2009).

[12] *See In re Kotzab,* 217 F.3d 1365, 1369 (Fed. Cir. 2000).

[13] *KSR v. Teleflex, 550 U.S. 398; 127 S. Ct. 1727 at 1741* (citing *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006)) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.")

facie case for the unpatentability Applicant's claims has been established *without any deference to the USPTO. Ex Parte Frye*, Appeal 2009-006013, pp. 9-10 (BPAI 2010) ("an applicant can overcome a rejection by showing insufficient evidence of *prima facie* [unpatentability] ... the Board reviews the particular finding(s) contested by an appellant *anew*.") (emphasis added).

The MPEP indicates that in order for an examiner to establish a *prima facie* case of anticipation of an applicant's claim, the examiner must first interpret the claim,[14] and thereafter show that the cited prior art discloses the same elements, in the same arrangement, as the elements of the claim which the examiner asserts is anticipated. More specifically, the MPEP states that "[a] claim is anticipated *only if each and every element as set forth in the claim is found*, either expressly or inherently described, in a single prior art reference. . . . The identical invention must be shown in as complete detail as is contained in the . . . claim. . . . The elements must be arranged as required by the claim . . . .". *MPEP* § 2131 (emphasis added). For example, In *McNeil,* the Examiner had rejected claims reciting a tampon having "a generally cylindrical compressed, solid fibre core" and ribs "compressed less than the fiber core" in view of a Japanese patent application ("Sasaki"). McNeil appealed to the Board of Patent Appeals and Interferences, which "specifically found that 'Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward.' " *See id.,* 2008-1546, slip op. 1, 3 (Fed. Cir. July 31, 2009). In light of this and its finding that of each rib of Sasaki being "compressed less than the fiber core," the Board affirmed the rejections. Insofar as the Sasaki reference did not directly disclose/recite as alleged by the Board, and since the Board did not supply evidence supporting its statement that "Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward," the Federal Circuit reversed the rejection for lack of "substantial evidentiary support," stating as follows:

[14] With respect to interpreting a claim at issue, the MPEP directs that, during examination — as opposed to subsequent to issue — such claim be interpreted as broadly as the claim terms would reasonably allow, in light of the specification, when read by one skilled in the art with which the claimed invention is most closely connected. *MPEP* § 2111.

> There is not substantial evidence, indeed, no evidence, that Sasaki discloses ribs "compressed less than the fiber core" or "a generally cylindrical compressed, solid fibre core." ... Just as the Sasaki figures do not indicate the relative compression of the different portions of the tampon, the Sasaki figures completely lack any indication of the relative coarseness of different portions. ... Lastly, turning to the issue of spacing of the ribs, Figure 8 shows a space between the bottommost ribs, and there is arguably some space shown between other ribs. However, because it is neither clear that Sasaki discloses a core nor which portions of Sasaki's tampon the Board considered to be the ribs and which the Board considered to be the core, we cannot say that substantial evidence supports the Board's determination that Sasaki discloses ribs separated from each other "at the proximal end by an amount greater than" than at "the distal end."

McNeil, 2008-1546, slip op. 1, 10-11 (Fed. Cir. July 31, 2009) (emphasis added).

In *In re Skvorecz*, an anticipation rejection rested on an interpretation of features of a wire stand. The claim at issue required that each wire leg of the stand have a laterally displacing offset. The BPAI admitted that in the cited reference, "Buff," the offset in the rim was not shown to be 'for laterally displacing each wire leg relative to said upper rim' as required by claim 1, but nonetheless maintained the rejection. The Federal Circuit reversed for lack of evidence:

> On rehearing the Board stated that Buff's wire 48 is a "transverse member" and not a wire leg, and therefore that it need not have a displacing offset. Mr. Skvorecz states, and we agree, that Buff's wire 48 is a leg of the Buff structure. The Board's contrary statement is unsupported by any evidence.

Id. at p. 8 (emphasis added).

Consequently, under the guidelines of the MPEP set forth above, if there is *any* substantial difference between the prior art cited by an examiner and an applicant's claim which the examiner asserts is rendered anticipated by the prior art, the prior art does NOT establish a *prima facie* case of anticipation and, barring other rejections, the applicant is entitled to a patent on such claim.

3. MPEP Standards for Determining Obviousness

"[T]he examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness."[15] *MPEP* § 2142. This initial burden is a cornerstone of examination principles and, as such, the Board ensures on appeal that a *prima facie* case for the unpatentability Applicant's claims has been established *without any deference to the USPTO. Ex Parte Frye*, Appeal 2009-006013, pp. 9-10 (BPAI 2010) ("an applicant can overcome a rejection by showing insufficient evidence of *prima facie* [unpatentability] ... the Board reviews the particular finding(s) contested by an appellant *anew*.") (emphasis added). The MPEP indicates that in order for an examiner to establish a *prima facie* case that an invention, as defined by a claim at issue, is obvious, the examiner must (1) interpret the claim at issue; (2) define one or more prior art reference components relevant to the claim at issue; (3) ascertain the differences between the one or more prior art reference components and the elements of the claim at issue; and (4) adduce objective evidence which establishes, under a preponderance of the evidence standard, a teaching to modify the teachings of the prior art reference components such that the prior art reference components can be used to construct a device substantially equivalent to the claim at issue. This last step generally encompasses two sub-steps: (1) adducement of objective evidence teaching how to modify the prior art components to achieve the individual elements of the claim at issue; and (2) adducement of objective evidence teaching how to combine the modified individual components such that the claim at issue, as a whole, is achieved. *MPEP* § 2141; *MPEP* § 2143. Each of these foregoing elements is further defined within the MPEP. *Id.*

This requirement has been explained recently by the Supreme Court in *KSR v. Teleflex,* 550 U.S. 398; 127 S. Ct. 1727 (2007) which noted that such a rejection requires "some articulated reasoning ... to support the legal conclusion of obviousness." As stated by the Court, obviousness can be established where "there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, ***this analysis should be made explicit***." (emphasis added). *See* In re Kahn, 441 F. 3d 977, 988 (CA Fed. 2006)

[15] An invention, as embodied in the claims, is rendered obvious if an Examiner concludes that although the claimed invention is not identically disclosed or described in a reference, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *MPEP* § 2141 (citing 35 U.S.C. § 103).

('[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.')." *KSR v. Teleflex,* 550 U.S. 398; 127 S. Ct. 1727 at 1741.

As further described by the Court ***"[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.*** Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *KSR v. Teleflex,* 550 U.S. 398; 127 S. Ct. 1727 at 1741.

a) Interpreting a Claim at Issue

With respect to interpreting a claim at issue, the MPEP directs that, during examination — as opposed to subsequent to issue — the pending claims must be "given their broadest reasonable interpretation consistent with the specification." MPEP § 2111. The Federal Circuit's *en banc* decision in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) expressly recognized that the USPTO employs the "broadest reasonable interpretation consistent with the specification" standard:

> The [PTO] determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004). Indeed, the rules of the PTO require that application claims must "conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description." 37 CFR 1.75(d)(1).

Phillips at 1316. See also *In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000) and MPEP § 2111.

In addition, it is the PTO's responsibility to interpret the claims during prosecution. *See In re Morris*, 127 F.3d 1048, 1054-55 (Fed. Cir. 1997) (the "PTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they

would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification."). See also Examination Guidelines For Determining Obviousness Under 35 U.S.C. § 103: MPEP § 2141, II, A.: "The scope of the claimed invention must be clearly determined by giving the claims the 'broadest reasonable interpretation consistent with the specification.' *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1316, 75 USPQ2d 1321, 1329 (Fed. Cir. 2005) and MPEP § 2111."

b) Definition of One or More Prior Art Reference Components Relevant to the Claim at Issue

Once the claim at issue has been properly interpreted, the next step is the definition of one or more prior art reference components (*e.g.*, electrical, mechanical, or other components set forth in a prior art reference) relevant to the properly interpreted claim at issue. With respect to the definition of one or more prior art reference components relevant to the claim at issue, the MPEP defines three proper sources of such prior art reference components, with the further requirement that each such source must have been extant at the time of invention to be considered relevant. These three sources are as follows: patents as defined by 35 U.S.C. § 102, printed publications as defined by 35 U.S.C. § 102, and information (*e.g.*, scientific principles) deemed to be "well known in the art"[16] as defined under 35 U.S.C. § 102. *MPEP* § 2141; *MPEP* § 2144.

[16] The fact that information deemed to be "well known in the art" can serve as a proper source of prior art reference components seems to open the door to subjectivity, but such is not the case. As a remedy to this potential problem, *MPEP* § 2144.03 states that if an Examiner asserts that his position is derived from and/or is supported by a teaching or suggestion that is alleged to have been "well known in the art," and that if an applicant traverses such an assertion (that something was "well known within the art"), the Examiner must cite a reference in support of his or her position. The same MPEP section also states that when a rejection is based on facts within the personal knowledge of an Examiner, the data should be stated as specifically as possible, and the facts must be supported, when called for by the applicant, by an affidavit from the Examiner. Such an affidavit is subject to contradiction or explanation by the affidavits of the applicant and other persons. *Id.* Thus, all sources of prior art reference components must be objectively verifiable.

c) Ascertainment of Differences between Prior Art Reference Components and Claim at Issue; Teaching to Modify and/or Combine Prior Art Reference Components to Remedy Those Differences in Order to Achieve Recitations of Claim at Issue

With one or more prior art components so defined and drawn from the proper prior art sources, the differences between the one or more prior art reference components and the elements of the claim at issue are to be ascertained. Thereafter, in order to establish a case of *prima facie* obviousness, an examiner must set forth a rationale, supported by objective evidence[17] sufficient to demonstrate under a preponderance of the evidence standard, that in the prior art extant at the time of invention there was a teaching to modify and/or combine the one or more prior art reference components to construct a device practicably equivalent to the claim at issue.

In *Kotzab*, insofar as the cited Evans reference did not directly disclose/recite as alleged by the Board, and since the Board did not supply evidence supporting its contention that "one system" is equal to "one sensor," the Federal Circuit reversed the rejection for lack of "necessary substantial evidence to support a rejection," stating as follows:

> The Examiner cites Evans for teaching that "one system constructed and operated according to the invention may be used to control a number of valves." Evans application, p. 19, ll. 6-8 (emphasis added). In view of this disclosure only, the Examiner concluded that Evans teaches the use of one sensor to control a number of valves. This conclusion must necessarily rest on the unstated premise by the Examiner that "one system" is equal to "one sensor."
>
> But the Board's decision, adopting the Examiner's premise, lacks the necessary substantial evidence to support a rejection of Kotzab's claims. Specifically, there is not substantial evidence to show that "one system" is the same thing as "one sensor." The words "sensor" and "probe" are used throughout Evans to refer to the device that measures the mold temperature. ... Evans clearly never uses the term "system" as a substitute for the simple temperature measuring device it calls "sensor." And, the Board made no reference to any evidence in the record that would equate "one system" with "one sensor."
>
> As mentioned previously, more than a mere scintilla of evidence is necessary to support the Board's implicit conclusion that "one system" is equal to "one sensor." Based on the entirety of Evans' disclosure, we cannot say that there is such

[17] The proper sources of the objective evidence supporting the rationale are the defined proper sources of prior art reference components, discussed above, with the addition of factually similar legal precedent. *MPEP* § 2144.

relevant evidence as a reasonable mind might accept as adequate to support the conclusion that "one system" means "one sensor."

See id., 217 F.3d 1365, 1370-71 (Fed. Cir. 2000) (emphasis added).

The preferable evidence relied upon is an express teaching to modify/combine within the properly defined objectively verifiable sources of prior art. In the absence of such express teaching, an examiner may attempt to establish a rationale to support a finding of such teaching reasoned from, or based upon, express teachings taken from the defined proper sources of such evidence (*i.e.*, properly defined objectively verifiable sources of prior art). *MPEP* § 2144; *In re Dembiczak*, 50 U.S.P.Q.2d 1614 (Fed. Cir. 1999).

The MPEP recognizes the pitfalls associated with the tendency to subconsciously use impermissible "hindsight" when an examiner attempts to establish such a rationale. The MPEP has set forth at least two rules to ensure against the likelihood of such impermissible use of hindsight. The first rule is that:

> under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information,[18] the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of an Applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search, and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon an Applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

MPEP § 2142 (emphasis added). Thus, if the only objective evidence of such teaching to modify and/or combine prior art reference components is an applicant's disclosure, no evidence of such teaching exists.[19]

[18] "Factual information" is information actually existing or occurring, as distinguished from mere supposition or opinion. *Black's Law Dictionary* 532 (5th ed. 1979).

[19] An applicant may argue that an Examiner's conclusion of obviousness is based on improper hindsight reasoning. However, "[a]ny judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." *MPEP* § 2145(X)(A) (emphasis added).

The second rule is that if an examiner attempts to rely on some advantage or expected beneficial result that would have been produced by a modification and/or combination of the prior art reference components as evidence to support a rationale to establish such teachings to modify and/or combine prior art reference components, the MPEP requires that such advantage or expected beneficial result be objectively verifiable teachings present in the acceptable sources of prior art (or drawn from a convincing line of reasoning based on objectively verifiable established scientific principles or teachings). *MPEP* § 2144. Thus, as a guide to avoid the use of impermissible hindsight, these rules from the MPEP make clear that absent some objective evidence, sufficient to persuade under a preponderance of the evidence standard, no teaching of such modification and/or combination exists.[20]

[20] *In Re Sang Su Lee* 277 F.3d 1338 (Fed. Cir. 2002) ("When patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness.") *See, e.g., McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351-52, 60 U.S.P.Q.2d 1001, 1008 (Fed. Cir. 2001) ("the central question is whether there is reason to combine [the] references," a question of fact drawing on the *Graham* factors). *"The factual inquiry whether to combine references must be thorough and searching." Id. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with. See, e.g., Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1124-25, 56 U.S.P.Q.2d 1456, 1459 (Fed. Cir. 2000) ("a showing of a suggestion, teaching, or motivation to combine the prior art references is an 'essential component of an obviousness holding'") (quoting *C.R. Bard, Inc., v. M3 Systems, Inc.*, 157 F.3d 1340, 1352, 48 U.S.P.Q.2d 1225, 1232 (Fed. Cir. 1998)); *In re Dembiczak*, 175 F.3d 994, 999, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999) ("Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references."); *In re Dance*, 160 F.3d 1339, 1343, 48 U.S.P.Q.2d 1635, 1637 (Fed. Cir. 1998) (there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant); *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988) ("'teachings of references can be combined only if there is some suggestion or incentive to do so.'") (emphasis in original) (quoting *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984)). The need for specificity pervades this authority. *See, e.g., In re Kotzab*, 217 F.3d 1365, 1371, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000) ("particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed"); *In re Rouffet*, 149 F.3d 1350, 1359, 47 U.S.P.Q.2d 1453, 1457-58 (Fed. Cir. 1998) ("even when the level of skill in the art is high, the Board must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination. In other words, the Board must explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious.")).

B. Technical Material Cited by the USPTO Does Not Show/Suggest Recitations of Independent Claim 1 and Dependent Claims 2-34 and 66-68 as Presented Herein; Notice of Allowance of Same Respectfully Requested

1. Independent Claim 1

Independent Claim 1 recites as follows:

1. A device for perfusion management, comprising:

[a] a body portion;

[b] at least one extensible finger coupled to said body portion, the extensible finger being composed of a plurality of retractable segments, the plurality of retractable segments of the extensible finger configured to controllably telescopically extend from the body portion;

[c] at least one reservoir in communication with said extensible finger; and

[d] a control circuitry coupled to said extensible finger, and/or said body portion.[21]

As shown following, (1) the USPTO-cited material fails to recite several express recitations of these claims; (2) the USPTO is asserting that each cited reference "teaches" at least some of the text of Independent Claim 1, but has not provided any objectively verifiable evidence supporting these assertions; and (3) the USPTO has failed to adduce objective evidence of how to modify/combine the cited art to match the recitations of Independent Claim 1. Moreover, Appellant maintains that such modifications/combinations would change the principle of operation of the cited art and/or render the cited art unfit for one or more of its intended purposes.

[21] The lettering of the clauses herein is merely for sake of clarity of argument and should not be taken to imply any particular ordering of the clauses.

2. Davison and Douk Do Not Show/Suggest Recitations of Independent Claim 1

a) Davison Fails to Recite Several Express Terms of Independent Claim 1 and Therefore the USPTO Has Not Met Its Burden to Establish a *Prima Facie* Case of Unpatentability for Independent Claim 1

Concerning this, the USPTO has recently stated as follows:

Davison et al disclose a device comprising a body portion (1); at least one extensible finger (42) coupled to said body portion; **at least one reservoir (32) in communication with said extensible finger;** and a control circuitry (Col. 17, lines 40-49) coupled to said body portion.

Davison et al. do not disclose, however, that the extensible finger is composed of a plurality of retractable segments which are configured to controllably telescopically extend from the body portion.

Douk teaches an implantable sheath catheter having a plurality of retractable segments (402, 403, 404) which are configured to controllably telescopically extend (via positioning wire 406: Figs. 4 and 5). Regarding claims 15 and 16, Douk further teaches that the plurality of retractable segments are configured to articulate at joints of adjacent segments (407-412, for example) and that the segments are hollow (Figs. 4 and 5). Further, regarding claims 66-68, the segments of Douk are configured to slidably collapse against adjacent segments (Fig. 5), impart length adjustability to the at least one extensible finger, and impart adjustability to the articulation of the at least one extensible finger (Figs. 4 and 5; the device can change in length, and the articulation of the segments changes based on whether the catheter is extended (Fig. 4), retracted (Fig. 5), or somewhere in between (not shown)).

At the time of the invention, it would have been obvious to one having ordinary skill in the art to substitute the extensible finger having a plurality of retractable segments of Douk for the extensible finger having a single segment of Davison et al, because doing so would allow the physician to change the length of the catheter during a procedure instead of being attached to a particular length chosen prior to the start of a surgical procedure.

Office Action, p. 8 (14 Oct 2009) (emphasis added). [22]

As set forth above, Independent Claim 1 recites as follows: "[c] **at least one reservoir in communication with said extensible finger**."

It appears to Appellant that the USPTO has mapped "[c] **at least one reservoir in communication with said extensible finger**" onto **probe 32**:

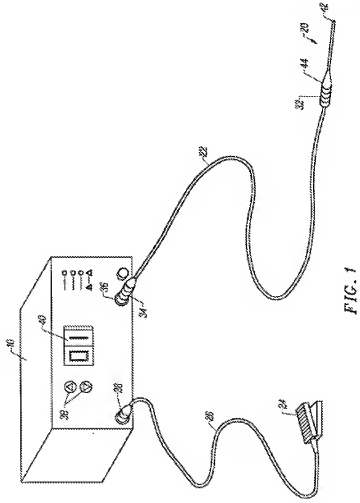

FIG. 1

[22] Appellant respectfully asserts that the USPTO has apparently not examined the recitations of Appellant's claims, but appears to have not addressed the express language of both Appellant's claims and the cited technical material. Accordingly, Appellant respectfully maintains that the USPTO has not established a *prima facie* case of the unpatentability of any pending claim for at least this reason. Notwithstanding the foregoing, Appellant demonstrates herein that even if the USPTO had followed the MPEP examination guidelines, no *prima facie* case of unpatentability would be extant.

Davison, Figure 1.

Appellant notes that the USPTO has not explained how it reaches such mappings under the broadest reasonable interpretation framework as is the USPTO's burden (e.g., such as by examples drawn from Appellant's claims or detailed description),[23] and furthermore, Appellant points out that this mapping does not address "**at least one reservoir in communication with said extensible finger**."

In view of the foregoing, Appellant points out that although Independent Claim 1 has been quoted in the present rejection, several claim terms have not been addressed in its analysis. Because the USPTO-cited material fails to recite at least the foregoing bolded recitations of Independent Claim 1,[24] under the MPEP guidelines as set forth above, such material does not establish a *prima facie* case of the unpatentability of Independent Claim 1. Accordingly, for at least the foregoing reasons, Appellant respectfully asks the Board to reverse the USPTO's rejections of Independent Claim 1 as being unpatentable, and hold Independent Claim 1 allowable and to issue a Notice of Allowance of same.

b) The USPTO is Characterizing/Asserting Davison to "Teach" the Text of Independent Claim 1, But Does Not Support Its Characterization/Assertion, Therefore the USPTO Has Not Met Its Burden to Establish a *Prima Facie* Case of Unpatentability for Independent Claim 1

The USPTO has stated as follows:

Davison et al disclose a device comprising a body portion (10); at least one extensible finger (42) coupled to said body portion; **at least one reservoir (32) in**

[23] Irrespective of a desire to be cooperative, the ability of any patent practitioner to help the Examiner fulfill this burden on the record is tightly curtailed by pre- and post-issuance legal standards and by various ethical duties in tension. *See, e.g.,* 37 C.F.R. § 10.83 ("A practitioner should represent a client zealously within the bounds of the law."); 37 C.F.R. § 10.84 ("[A] practitioner shall not intentionally … [p]rejudice or damage a client during the course of a professional relationship, except as required under this [ethics] part."); and 37 C.F.R. § 10.76 ("A practitioner should represent a client competently."). For these and other reasons, this document notes instances in which the USPTO did not follow the prescribed rules rather than seeking to interpret claims and/or to adduce evidence on the USPTO's behalf.

[24] Although Independent Claim 1 has been quoted in the present rejection, several claim terms have not been addressed in its analysis, as shown below.

communication with said extensible finger; and a control circuitry (Col. 17, lines 40-49) coupled to said body portion.

Davison et al. do not disclose, however, that the extensible finger is composed of a plurality of retractable segments which are configured to controllably telescopically extend from the body portion.

Douk teaches an implantable sheath catheter having a plurality of retractable segments (402, 403, 404) which are configured to controllably telescopically extend (via positioning wire 406: Figs. 4 and 5). Regarding claims 15 and 16, Douk further teaches that the plurality of retractable segments are configured to articulate at joints of adjacent segments (407-412, for example) and that the segments are hollow (Figs. 4 and 5). Further, regarding claims 66-68, the segments of Douk are configured to slidably collapse against adjacent segments (Fig. 5), impart length adjustability to the at least one extensible finger, and impart adjustability to the articulation of the at least one extensible finger (Figs. 4 and 5; the device can change in length, and the articulation of the segments changes based on whether the catheter is extended (Fig. 4), retracted (Fig. 5), or somewhere in between (not shown)).

At the time of the invention, it would have been obvious to one having ordinary skill in the art to substitute the extensible finger having a plurality of retractable segments of Douk for the extensible finger having a single segment of Davison et al, because doing so would allow the physician to change the length of the catheter during a procedure instead of being attached to a particular length chosen prior to the start of a surgical procedure.

Office Action, p. 8 (14 Oct 2009). [25] Appellant respectfully disagrees and traverses the rejection.

[25] Appellant respectfully asserts that the USPTO has apparently not examined the recitations of Appellant's claims, but appears to have not addressed the express language of both Appellant's claims and the cited technical material. Accordingly, Appellant respectfully maintains that the USPTO has not established a *prima facie* case of the unpatentability of any pending claim for at least this reason. Notwithstanding the foregoing, Appellant demonstrates herein that even if the USPTO had followed the MPEP examination guidelines, no *prima facie* case of unpatentability would be extant.

(1) The USPTO Has Put Forth No Evidence Supporting Its Characterization/Assertion That Davison "Teaches" Recitations of Independent Claim 1

Appellant respectfully points out that Appellant has reviewed the Davison reference identified by the USPTO, and so far as Appellant can discern, the Davison reference does not recite "[c] **at least one reservoir in communication with said extensible finger**" as recited in Appellant's Independent Claim 1.[26] Rather, the portions of Davison cited by the USPTO actually recite as follows:

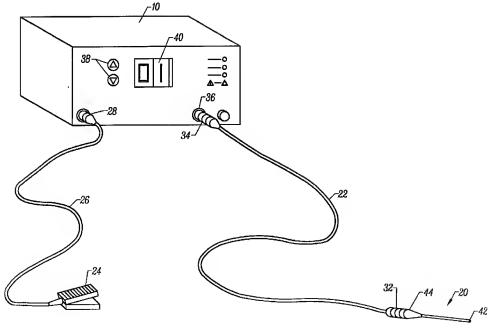

FIG. 1

[26] Nor does Davison recite as the USPTO alleges, for that matter; Appellant again points out that, in derogation of the MPEP guidelines, the USPTO has not addressed the language of Appellant's Independent Claim 1.

Power supply 10 has an operator controllable voltage level adjustment 38 to change the applied voltage level, which is 10 observable at a voltage level display 40. Power supply 10 also includes one or more foot pedals 24 and a cable 26 which is removably coupled to a receptacle 30 with a cable connector 28. The foot pedal 24 may also include a second pedal (not shown) for remotely adjusting the energy level applied to electrode terminals 104, and a third pedal (also not shown) for switching between an ablation mode and a coagulation mode.

Davison, Figure 1 and Col. 17, Lines 40-49.

The USPTO is characterizing Davison to "teach" at least some of the text of Independent Claim 1, but does not support its characterization with objectively verifiable evidence. The USPTO has therefore not met its burden to establish a *prima facie* case of unpatentability for Independent Claim 1. What a reference "teaches" is a question of fact.[27,28,29] Conclusory statements that a reference "teaches" something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such "teachings" unless they are supported by objective evidence. *See In re McNeil-PPC,* 2008-1546 (Fed. Cir. July 31, 2009);[30] *In re Lee,* 277 F.3d

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[27] *See Rapoport v. Dement,* 254 F.3d 1053, 1060 (Fed. Cir. 2001) ("What a reference teaches is a question of fact... Therefore, we review the Board's characterization of the disclosure in the FPR Publication for substantial evidence.") (emphasis added).

[28] *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO and holding when the PTO presented no evidence to cure *prima facie* differences between patent claim and Examiner assertions regarding what the allegedly invalidating prior art "taught")

[29] Anticipation, as well as what a reference teaches, is a question of fact. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002).

[30] In *McNeil,* the Examiner had rejected claims reciting a tampon having "a generally cylindrical compressed, solid fibre core" and ribs "compressed less than the fiber core" in view of a Japanese patent application ("Sasaki"). McNeil appealed to the Board of Patent Appeals and Interferences, which "specifically found that 'Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward.' " *See id.,* 2008-1546, slip op. 1, 3 (Fed. Cir. July 31, 2009). In light of this and its finding that of each rib of Sasaki being "compressed less than the fiber core," the Board affirmed the rejections. Insofar that the Sasaki reference did not directly disclose/recite as alleged by the Board, and since the Board did not supply evidence supporting its statement that "Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward," the Federal Circuit reversed the rejection for lack of "substantial evidentiary support," stating as follows:

> There is not substantial evidence, indeed, no evidence, that Sasaki discloses ribs "compressed less than the fiber core" or "a generally cylindrical compressed, solid fibre core." ... Just as the Sasaki figures do not indicate the relative compression of the different portions of the tampon, the Sasaki figures completely lack any indication of the relative coarseness of different portions. ... Lastly, turning to the issue of spacing of the ribs, Figure 8 shows a space between the bottommost ribs, and there is arguably some space shown between other ribs. However, because it is neither clear that Sasaki discloses a core nor which portions of

1338 (Fed. Cir. 2002);[31] *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000) ("Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto. … Broad conclusory statements standing alone are not "evidence.").[32] Even if the PTO personnel were to seek to support their characterizations with an expert witness affidavit, the law is that conclusory statements by an expert that a reference "teaches" something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such "teachings" unless they are supported by objective documentary evidence.[33] Thus, when a party to a matter asserts that a

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> Sasaki's tampon the Board considered to be the ribs and which the Board considered to be the core, we cannot say that substantial evidence supports the Board's determination that Sasaki discloses ribs separated from each other "at the proximal end by an amount greater than" than at "the distal end."

See id., 2008-1546, slip op. 1, 10-11 (Fed. Cir. July 31, 2009).

[31] In *Lee*, the USPTO argued that, to the "common sense of a person of ordinary skill in the art," it was obvious that one could combine a prior patent for an on-screen television menu with an on-screen picture-quality adjustment for a video game played on a television illustrated in the game's handbook. The Federal Circuit ruled that obviousness must be based on "objective evidence of record." Finding no specific published suggestion in the record, the Federal Circuit ruled the invention patentable. *See id.*, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (describing the BPAI's obligation to develop an evidentiary basis for its factual findings to allow for meaningful judicial review under the substantial evidence standard).

[32] In *Kotzab*, the Federal Circuit reversed the BPAI as follows:

> The Examiner cites Evans for teaching that "one *system* constructed and operated according to the invention may be used to control a number of valves." Evans application, p. 19, ll. 6-8 (emphasis added). In view of this disclosure only, the Examiner concluded that Evans teaches the use of one *sensor* to control a number of valves. This conclusion must necessarily rest on the unstated premise by the Examiner that "one system" is equal to "one sensor."
>
> But the Board's decision, adopting the Examiner's premise, lacks the necessary substantial evidence to support a rejection of Kotzab's claims. Specifically, there is not substantial evidence to show that "one system" is the same thing as "one sensor." The words "sensor" and "probe" are used throughout Evans to refer to the device that measures the mold temperature. … Evans clearly never uses the term "system" as a substitute for the simple temperature measuring device it calls "sensor." And, the Board made no reference to any evidence in the record that would equate "one system" with "one sensor."
>
> As mentioned previously, more than a mere scintilla of evidence is necessary to support the Board's implicit conclusion that "one system" is equal to "one sensor." Based on the entirety of Evans' disclosure, we cannot say that there is such relevant evidence as a reasonable mind might accept as adequate to support the conclusion that "one system" means "one sensor."

See id., 217 F.3d 1365, 1370-71 (Fed. Cir. 2000) (underline added).

[33] *See Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1473 (Fed. Cir. 1997) ("The district court's holding misapprehends the rigors of anticipation. For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art... **Although this disclosure requirement presupposes the knowledge of one skilled in the art of the claimed invention, that presumed knowledge does not grant a license to read into the prior art reference teachings that are not there.**

reference "teaches" something beyond its bare recitations/direct disclosure, and that factual assertion is challenged by an opposite party, the law requires that the asserting party provide objective evidentiary support to "close the gap" between what the reference recites and the what the asserting party *alleges* the reference teaches; in the absence of such evidence, there should be no finding of fact in favor of the asserted teaching.[34,35,36,37] For each instance below in which the USPTO has made an unsupported characterization, Appellant accordingly has requested without response that the USPTO either (1) withdraw the corresponding claim rejection or (2) provide an affidavit setting forth objectively verifiable evidence sufficient to "close the gap" between the characterization and what the reference actually recites.

As can be seen from the foregoing, for example, the USPTO-identified portions of Davison do *not recite* the text of at least Clause [c] of Independent Claim 1: "**at least one reservoir in communication with said extensible finger.**"

Instead, Davison further recites in reference to Figure 1 above that:

An expert's conclusory testimony, unsupported by the documentary evidence, cannot supplant the requirement of anticipatory disclosure in the prior art reference itself.") (emphasis added); *see also Genzyme Corp. v. Atrium Med. Corp.,* 315 F. Supp. 2d 552, 563 (D. Del. 2004) ("For a patent to be anticipated, every element of a patent claim must appear in a single reference. **Other references and opinion may be used to reveal what the reference would have meant to those skilled in the art at the time of the invention**.... **For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art. Presumed knowledge of one skilled in the art does not allow an expert to read into the reference elements that are not there.**") (emphasis added)

[34] *See Rapoport v. Dement* 254 f. 3rd 1053, 1060 (Fed. Cir. 2001) . In *Rapoport,* the Federal Circuit affirmed the Board's holding that a publication did not anticipate a claim, reasoning as follows (emphasis added):

> Having construed the disputed term in the interference count and affirmed the Board's interpretation, we can properly address the merits of Rapoport's anticipation argument. The Board found that the disclosure of the FPR Publication was limited to treatment of anxiety in patients suffering from sleep apnea with buspirone, and did not address treatment of the underlying sleep apnea disorder. What a reference **teaches** is a question of fact.... There is no disclosure in the FPR Publication of tests in which buspirone is administered to patients suffering from sleep apnea with the intent to cure the underlying condition.... The Board also correctly found that the FPR Publication does not show administering buspirone in any specific amounts to patients suffering from sleep apnea.... We note that there is no mention in the FRP Publication of administering buspirone to a patient at bedtime.... Therefore, for all the reasons stated above, we find that the Board's conclusion that the FPR Publication does not disclose administration of buspirone to patients suffering from sleep apnea to treat sleep apnea is supported by substantial evidence.

[35] *See In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO's holding that a gene was "prima facie obvious over its corresponding protein" in the cited reference, absent any evidence of a one-to-one correspondence).

[36] *See In re McNeil-PPC,* 2008-1546 (Fed. Cir. July 31, 2009).

[37] *See In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

> Referring now to FIG. 1, an exemplary **electrosurgical system 5 for resection, ablation, coagulation and/or contraction of tissue** will now be described in detail. As shown, **electrosurgical system 5 generally includes an electrosurgical probe 20 connected to a power supply 10 for providing high frequency voltage to one or more electrode terminals and a loop electrode** (not shown in FIG. 1) on probe 20. Probe 20 includes a connector housing 44 at its proximal end, which can be removably connected to a probe receptacle 32 of a probe cable 22. The proximal portion of cable 22 has a connector 34 to couple probe 20 to power supply 10. Power supply 10 has an operator controllable **voltage level adjustment 38 to change the applied voltage level**, which is 10 observable at a voltage level display 40. Power supply 10 also includes one or more foot pedals 24 and a cable 26 which is removably coupled to a receptacle 30 with a cable connector 28. The foot pedal 24 may also include a second pedal (not shown) for remotely **adjusting the energy level applied to electrode terminals** 104, and a third pedal (also not shown) for **switching between an ablation mode and a coagulation mode**.
>
> *Davison*, Col. 17, Lines 29-49 (emphasis added).

Appellant has shown by direct quotations that Independent Claim 1 and the Davison reference are very different on their faces. *See supra* (quotation of Claim 1 and quotation of Davison). Insofar that Appellant has shown that *"at first sight; on the first appearance; on the face of it; so far as can be judged from the first disclosure"* the USPTO-cited art is very different from Claim 1, and Appellant has noted that the USPTO has not cited to any objectively verifiable evidence/argument based on same sufficient to remedy such *prima facie* differences, the USPTO-cited technical material does not establish a *prima facie* case of the unpatentability of Claim 1 either under the MPEP or under controlling legal standards. *See supra.*

Accordingly, insofar as that Davison does not recite the text of at least Clause [c] of Appellant's Independent Claim 1, and insofar as that the USPTO has provided no objectively verifiable evidence, or argument based on objectively verifiable evidence, as to how Davison could be modified/combined to teach at least Clause [c] of Independent Claim 1, Appellant respectfully points out that under the MPEP guidelines as set forth above, the USPTO-cited technical material does not a establish a *prima facie* case of the unpatentability of Independent Claim 1 for at least these reasons. Accordingly, for at least the foregoing reasons, Appellant respectfully asks the Board to reverse the USPTO's rejections of Independent Claim 1 as being unpatentable, and hold Independent Claim 1 allowable and to issue a Notice of Allowance of same.

c) Modifications/Combinations to Meet the Recitations of Independent Claim 1 Change the Principle of Operation of Components of Cited References; No Teaching to Combine/Modify Components as a Matter of Law.

In addition and/or in the alternative to the foregoing, Appellant additionally points out that, not only has the USPTO failed to adduce any objectively verifiable evidence sufficient to support the USPTO assertions regarding alleged teaching to modify/combine Davison to meet the recitations of Independent Claim 1, there can be no such teaching as a matter of law. Specifically, shown following is that under the MPEP standards there can be no teaching to modify/combine the technology of Davison as suggested by the USPTO in that the proposed modification/combination changes the principle of operation of the technology.

(1) Modifications to Meet the Recitations of Independent Claim 1 Change the Principle of Operation of Components Being Modified; No Teaching to Modify/Combine Components as a Matter of Law.

With respect to this point, Appellant respectfully directs the Board to *MPEP* § 2143.01, Suggestion or Motivation to Modify the References, which states as follows (emphasis added):

> THE PROPOSED MODIFICATION CANNOT CHANGE THE PRINCIPLE OF OPERATION OF A REFERENCE
>
> If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (Claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers inserted in a resilient sealing member. The primary reference relied upon in a rejection based on a combination of references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing. Patentee taught the device required rigidity for operation, whereas the claimed invention required resiliency. The court reversed the rejection holding the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic

principle under which the [primary reference] construction was designed to operate." 270 F.2d at 813, 123 USPQ at 352.).

Appellant respectfully asserts that one reason for Davison's lack of disclosure of "[c] **at least one reservoir in communication with said extensible finger"** may be gleaned from principles of operation indicated in this recitation:

> Referring now to FIG. 1, an exemplary **electrosurgical system 5 for resection, ablation, coagulation and/or contraction of tissue** will now be described in detail. As shown, **electrosurgical system 5 generally includes an electrosurgical probe 20 connected to a power supply 10 for providing high frequency voltage to one or more electrode terminals and a loop electrode** (not shown in FIG. 1) on probe 20. Probe 20 includes a connector housing 44 at its proximal end, which can be removably connected to a probe receptacle 32 of a probe cable 22. The proximal portion of cable 22 has a connector 34 to couple probe 20 to power supply 10. Power supply 10 has an operator controllable **voltage level adjustment 38 to change the applied voltage level**, which is 10 observable at a voltage level display 40. Power supply 10 also includes one or more foot pedals 24 and a cable 26 which is removably coupled to a receptacle 30 with a cable connector 28. The foot pedal 24 may also include a second pedal (not shown) for remotely **adjusting the energy level applied to electrode terminals** 104, and a third pedal (also not shown) for **switching between an ablation mode and a coagulation mode**.
>
> *Davison*, Col. 17, Lines 29-49 (emphasis added).

Appellant respectfully points out that were one to incorporate "[c] **at least one reservoir in communication with said extensible finger**" of Claim 1 into the structure of Davison, Davison would no longer provide "**an electrosurgical probe 20 connected to a power supply 10.**" Thus, any modifications/combinations would change the principle of operation of Davison for at least this reason.

As discussed above, one reason why such modified Davison technology would be rendered unsatisfactory is that, at present, the USPTO has not yet provided any teaching of how to modify/combine the Davison technology to provide "[c] **at least one reservoir in communication with said extensible finger**" as recited in Independent Claim 1. Hence, there would need to be some type of reconstruction and/or redesign of Davison.

As has been shown above, any modification of Davison would require "substantial reconstruction and redesign of the elements shown in [... Davison] as well as a change in the basic principle under which the [... Davison] construction was designed to operate" in order to reach the recitations of Claim 1. Accordingly, insofar as that any modification to Davison would likely require at least one additional and as-yet-hypothetical modification as explained above, under the MPEP standards set forth in block quote above, modification/combination "would change the principle of operation" of Davison.

Insofar as that any modification/combination would itself require *substantial* hypothetical reconstruction and/or redesign to render Davison capable of performing the intended purposes, under the MPEP guidelines as set forth above, the theory of operation of the technologies of Davison will have been changed. Consequently, under the MPEP standards as set forth above there can be no teaching to modify/combine such reference to meet the recitations of Independent Claim 1 as a matter of law. Accordingly, for at least the foregoing reasons, Appellant respectfully asks the Board to reverse the USPTO's rejections of Independent Claim 1 as being unpatentable, and hold Independent Claim 1 allowable and to issue a Notice of Allowance of same.

3. Adair and Douk Do Not Show/Suggest Recitations of Independent Claim 1

a) Adair Fails to Recite Several Express Terms of Independent Claim 1 and Therefore the USPTO Has Not Met Its Burden to Establish a *Prima Facie* Case of Unpatentability for Independent Claim 1

Concerning this, the USPTO has recently stated as follows:

> Adair teaches a body (handle), an extending part (probe), at least one receiving body (syringe) and **a control circuit.**
>
> Adair does not disclose, however, that the extensible finger is composed of a plurality of retractable segments which are configured to controllably telescopically extend from the body portion.

Douk teaches an implantable sheath catheter having a plurality of retractable segments (402, 403, 404) which are configured to controllably telescopically extend (via positioning wire 406: Figs. 4 and 5). Regarding claims 15 and 16, Douk further teaches that the plurality of retractable segments are configured to articulate at joints of adjacent segments (407-412, for example) and that the segments are hollow (Figs. 4 and 5). Further, regarding claims 66-68, the segments of Douk are configured to slidably collapse against adjacent segments (Fig. 5), impart length adjustability to the at least one extensible finger, and impart adjustability to the articulation of the at least one extensible finger (Figs. 4 and 5; the device can change in length, and the articulation of the segments changes based on whether the catheter is extended (Fig. 4), retracted (Fig. 5), or somewhere in between (not shown)).

At the time of the invention, it would have been obvious to one having ordinary skill in the art to substitute the extensible finger having a plurality of retractable segments of Douk for the extensible finger having a single segment of Adair, because doing so would allow the physician to change the length of the catheter during a procedure instead of being attached to a particular length chosen prior to the start of a surgical procedure.

Office Action, p. 10 (14 Oct 2009). [38]

As set forth above, Independent Claim 1 recites as follows: "[d] **a control circuitry coupled to said extensible finger, and/or said body portion**."

It appears to Appellant that the USPTO has mapped "[d] **a control circuitry coupled to said extensible finger, and/or said body portion**" onto "**a control circuit**."

Appellant notes that the USPTO has not explained how it reaches such mappings under the broadest reasonable interpretation framework as is the USPTO's burden (e.g., such as by examples drawn from Appellant's claims or detailed description),[39] and furthermore, Appellant

[38] Appellant respectfully asserts that the USPTO has apparently not examined the recitations of Appellant's claims, but appears to have not addressed the express language of both Appellant's claims and the cited technical material. Accordingly, Appellant respectfully maintains that the USPTO has not established a *prima facie* case of the unpatentability of any pending claim for at least this reason. Notwithstanding the foregoing, Appellant demonstrates herein that even if the USPTO had followed the MPEP examination guidelines, no *prima facie* case of unpatentability would be extant.

[39] Irrespective of a desire to be cooperative, the ability of any patent practitioner to help the Examiner fulfill this burden on the record is tightly curtailed by pre- and post-issuance legal standards and by various ethical duties in tension. *See, e.g.*, 37 C.F.R. § 10.83 ("A practitioner should represent a client zealously within the bounds of the law."); 37 C.F.R. § 10.84 ("[A] practitioner shall not intentionally … [p]rejudice or damage a client during the course of a professional relationship, except as required under this [ethics] part."); and 37 C.F.R. § 10.76 ("A practitioner should represent a client competently."). For these and other reasons, this document notes instances in

points out that this mapping does not address "**a control circuitry coupled to said extensible finger, and/or said body portion**."

In view of the foregoing, Appellant points out that although Independent Claim 1 has been quoted in the present rejection, several claim terms have not been addressed in its analysis. Because the USPTO-cited material fails to recite at least the foregoing bolded recitations of Independent Claim 1,[40] under the MPEP guidelines as set forth above, such material does not establish a *prima facie* case of the unpatentability of Independent Claim 1. Accordingly, for at least the foregoing reasons, Appellant respectfully asks the Board to reverse the USPTO's rejections of Independent Claim 1 as being unpatentable, and hold Independent Claim 1 allowable and to issue a Notice of Allowance of same.

b) The USPTO is Characterizing/Asserting Adair and Douk to "Teach" the Text of Independent Claim 1, But Does Not Support Its Characterization/Assertion, Therefore the USPTO Has Not Met Its Burden to Establish a *Prima Facie* Case of Unpatentability for Independent Claim 1

The USPTO has stated as follows:

> Adair teaches a body (handle), an extending part (probe), at least one receiving body (syringe) **and a control circuit.**
>
> Adair does not disclose, however, that the extensible finger is composed of a plurality of retractable segments which are configured to controllably telescopically extend from the body portion.
>
> Douk teaches an implantable sheath catheter having a plurality of retractable segments (402, 403, 404) which are configured to controllably telescopically extend (via positioning wire 406: Figs. 4 and 5). Regarding claims 15 and 16, Douk further teaches that the plurality of retractable segments are configured to articulate at joints of adjacent segments (407-412, for example) and that the segments are hollow (Figs. 4 and 5). Further, regarding claims 66-68, the segments of Douk are configured to slidably collapse against adjacent segments

which the USPTO did not follow the prescribed rules rather than seeking to interpret claims and/or to adduce evidence on the USPTO's behalf.

[40] Although Independent Claim 1 has been quoted in the present rejection, several claim terms have not been addressed in its analysis, as shown below.

(Fig. 5), impart length adjustability to the at least one extensible finger, and impart adjustability to the articulation of the at least one extensible finger (Figs. 4 and 5; the device can change in length, and the articulation of the segments changes based on whether the catheter is extended (Fig. 4), retracted (Fig. 5), or somewhere in between (not shown)).

At the time of the invention, it would have been obvious to one having ordinary skill in the art to substitute the extensible finger having a plurality of retractable segments of Douk for the extensible finger having a single segment of Adair, because doing so would allow the physician to change the length of the catheter during a procedure instead of being attached to a particular length chosen prior to the start of a surgical procedure.

Office Action, p. 10 (14 Oct 2009).[41] Appellant respectfully disagrees and traverses the rejection.

(1) The USPTO Has Put Forth No Evidence Supporting Its Characterization/Assertion That Adair "Teaches" Recitations of Independent Claim 1

Appellant respectfully points out that Appellant has reviewed the Adair reference identified by the USPTO, and so far as Appellant can discern, the Adair reference does not recite "[d] **a control circuitry coupled to said extensible finger, and/or said body portion**" as recited in Appellant's Independent Claim 1.[42] Rather, the portions of Adair cited by the USPTO actually recite as follows:

USPTO did not cite to any portions of Adair.

The USPTO is characterizing Adair to "teach" at least some of the text of Independent Claim 1, but does not support its characterization with objectively verifiable evidence. The

[41] Appellant respectfully asserts that the USPTO has apparently not examined the recitations of Appellant's claims, but appears to have not addressed the express language of both Appellant's claims and the cited technical material. Accordingly, Appellant respectfully maintains that the USPTO has not established a *prima facie* case of the unpatentability of any pending claim for at least this reason. Notwithstanding the foregoing, Appellant demonstrates herein that even if the USPTO had followed the MPEP examination guidelines, no *prima facie* case of unpatentability would be extant.

[42] Nor does Adair recite as the USPTO alleges, for that matter; Appellant again points out that, in derogation of the MPEP guidelines, the USPTO has not addressed the language of Appellant's Independent Claim 1.

USPTO has therefore not met its burden to establish a *prima facie* case of unpatentability for Independent Claim 1. What a reference "teaches" is a question of fact.[43,44,45] Conclusory statements that a reference "teaches" something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such "teachings" unless they are supported by objective evidence. *See In re McNeil-PPC,* 2008-1546 (Fed. Cir. July 31, 2009);[46] *In re Lee,* 277 F.3d 1338 (Fed. Cir. 2002);[47] *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000) ("Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto.

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[43] *See Rapoport v. Dement,* 254 F.3d 1053, 1060 (Fed. Cir. 2001) ("What a reference **teaches** is a question of fact,... Therefore, we review the Board's **characterization** of the **disclosure** in the FPR Publication for **substantial evidence**.") (emphasis added).

[44] *In re Bell***,** 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO and holding when the PTO presented no evidence to cure *prima facie* differences between patent claim and Examiner assertions regarding what the allegedly invalidating prior art "taught")

[45] Anticipation**,** as well as what a reference teaches**,** is a question of fact. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002).

[46] In *McNeil,* the Examiner had rejected claims reciting a tampon having "a generally cylindrical compressed, solid fibre core" and ribs "compressed less than the fiber core" in view of a Japanese patent application ("Sasaki"). McNeil appealed to the Board of Patent Appeals and Interferences, which "specifically found that 'Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward.' " *See id.,* 2008-1546, slip op. 1, 3 (Fed. Cir. July 31, 2009). In light of this and its finding that of each rib of Sasaki being "compressed less than the fiber core," the Board affirmed the rejections. Insofar that the Sasaki reference did not directly disclose/recite as alleged by the Board, and since the Board did not supply evidence supporting its statement that "Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward," the Federal Circuit reversed the rejection for lack of "substantial evidentiary support," stating as follows:

> There is not substantial evidence, indeed, no evidence, that Sasaki discloses ribs "compressed less than the fiber core" or "a generally cylindrical compressed, solid fibre core." ... Just as the Sasaki figures do not indicate the relative compression of the different portions of the tampon, the Sasaki figures completely lack any indication of the relative coarseness of different portions. ... Lastly, turning to the issue of spacing of the ribs, Figure 8 shows a space between the bottommost ribs, and there is arguably some space shown between other ribs. However, because it is neither clear that Sasaki discloses a core nor which portions of Sasaki's tampon the Board considered to be the ribs and which the Board considered to be the core, we cannot say that substantial evidence supports the Board's determination that Sasaki discloses ribs separated from each other "at the proximal end by an amount greater than" than at "the distal end."

See id., 2008-1546, slip op. 1, 10-11 (Fed. Cir. July 31, 2009).

[47] In *Lee,* the USPTO argued that, to the "common sense of a person of ordinary skill in the art," it was obvious that one could combine a prior patent for an on-screen television menu with an on-screen picture-quality adjustment for a video game played on a television illustrated in the game's handbook. The Federal Circuit ruled that obviousness must be based on "objective evidence of record." Finding no specific published suggestion in the record, the Federal Circuit ruled the invention patentable. *See id.,* 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (describing the BPAI's obligation to develop an evidentiary basis for its factual findings to allow for meaningful judicial review under the substantial evidence standard).

… Broad conclusory statements standing alone are not "evidence.").[48] Even if the PTO personnel were to seek to support their characterizations with an expert witness affidavit, the law is that conclusory statements by an expert that a reference "teaches" something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such "teachings" unless they are supported by objective documentary evidence.[49] Thus, when a party to a matter asserts that a reference "teaches" something beyond its bare recitations/direct disclosure, and that factual assertion is challenged by an opposite party, the law requires that the asserting party provide objective evidentiary support to "close the gap" between what the reference recites and the what the asserting party *alleges* the reference teaches; in the absence of such evidence, there should be

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[48] In *Kotzab*, the Federal Circuit reversed the BPAI as follows:

> The Examiner cites Evans for teaching that "one *system* constructed and operated according to the invention may be used to control a number of valves." Evans application, p. 19, ll. 6-8 (emphasis added). In view of this disclosure only, the Examiner concluded that Evans teaches the use of one *sensor* to control a number of valves. This conclusion must necessarily rest on the unstated premise by the Examiner that "one system" is equal to "one sensor."
>
> But the Board's decision, adopting the Examiner's premise, lacks the necessary substantial evidence to support a rejection of Kotzab's claims. Specifically, there is not substantial evidence to show that "one system" is the same thing as "one sensor." The words "sensor" and "probe" are used throughout Evans to refer to the device that measures the mold temperature. … Evans clearly never uses the term "system" as a substitute for the simple temperature measuring device it calls "sensor." And, the Board made no reference to any evidence in the record that would equate "one system" with "one sensor."
>
> As mentioned previously, more than a mere scintilla of evidence is necessary to support the Board's implicit conclusion that "one system" is equal to "one sensor." Based on the entirety of Evans' disclosure, we cannot say that there is such relevant evidence as a reasonable mind might accept as adequate to support the conclusion that "one system" means "one sensor."

See id., 217 F.3d 1365, 1370-71 (Fed. Cir. 2000) (underline added).

[49] *See Motorola, Inc. v. Interdigital Tech. Corp.,* 121 F.3d 1461, 1473 (Fed. Cir. 1997) ("The district court's holding misapprehends the rigors of anticipation. For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art... **Although this disclosure requirement presupposes the knowledge of one skilled in the art of the claimed invention, that presumed knowledge does not grant a license to read into the prior art reference teachings that are not there. An expert's conclusory testimony, unsupported by the documentary evidence, cannot supplant the requirement of anticipatory disclosure in the prior art reference itself.**") (emphasis added); *see also Genzyme Corp. v. Atrium Med. Corp.,* 315 F. Supp. 2d 552, 563 (D. Del. 2004) ("For a patent to be anticipated, every element of a patent claim must appear in a single reference. **Other references and opinion may be used to reveal what the reference would have meant to those skilled in the art at the time of the invention.... For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art. Presumed knowledge of one skilled in the art does not allow an expert to read into the reference elements that are not there.**") (emphasis added)

no finding of fact in favor of the asserted teaching.[50,51,52,53] For each instance below in which the USPTO has made an unsupported characterization, Appellant accordingly has requested without response that the USPTO either (1) withdraw the corresponding claim rejection or (2) provide an affidavit setting forth objectively verifiable evidence sufficient to "close the gap" between the characterization and what the reference actually recites.

As can be seen from the foregoing, the **USPTO did not identify any portions of Adair** that recite the text of at least Clause [d] of Independent Claim 1: "**a control circuitry coupled to said extensible finger, and/or said body portion.**"

Accordingly, insofar as that Adair does not recite the text of at least Clause [d] of Appellant's Independent Claim 1, and insofar as that the USPTO has provided no objectively verifiable evidence, or argument based on objectively verifiable evidence, as to how Adair could be modified/combined to teach at least Clause [d] of Independent Claim 1, Appellant respectfully points out that under the MPEP guidelines as set forth above, the USPTO-cited technical material does not a establish a *prima facie* case of the unpatentability of Independent Claim 1 for at least these reasons. Accordingly, for at least the foregoing reasons, Appellant respectfully asks the Board to reverse the USPTO's rejections of Independent Claim 1 as being unpatentable, and hold Independent Claim 1 allowable and to issue a Notice of Allowance of same.

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[50] *See Rapoport v. Dement* 254 f. 3rd 1053, 1060 (Fed. Cir. 2001) . In *Rapoport,* the Federal Circuit affirmed the Board's holding that a publication did not anticipate a claim, reasoning as follows (emphasis added):

> Having construed the disputed term in the interference count and affirmed the Board's interpretation, we can properly address the merits of Rapoport's anticipation argument. The Board found that the disclosure of the FPR Publication was limited to treatment of anxiety in patients suffering from sleep apnea with buspirone, and did not address treatment of the underlying sleep apnea disorder. What a reference **teaches** is a question of fact.... There is no disclosure in the FPR Publication of tests in which buspirone is administered to patients suffering from sleep apnea with the intent to cure the underlying condition.... The Board also correctly found that the FPR Publication does not show administering buspirone in any specific amounts to patients suffering from sleep apnea.... We note that there is no mention in the FRP Publication of administering buspirone to a patient at bedtime.... Therefore, for all the reasons stated above, we find that the Board's conclusion that the FPR Publication does not disclose administration of buspirone to patients suffering from sleep apnea to treat sleep apnea is supported by substantial evidence.

[51] *See In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO's holding that a gene was "prima facie obvious over its corresponding protein" in the cited reference, absent any evidence of a one-to-one correspondence).

[52] *See In re McNeil-PPC,* 2008-1546 (Fed. Cir. July 31, 2009).

[53] *See In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

4. Lebel and Douk Do Not Show/Suggest Recitations of Independent Claim 1

a) Modifications/Combinations to Meet the Recitations of Independent Claim 1 are Conclusory Statements; Change the Principle of Operation of Components of Cited References; and Render Cited References Unfit for Intended Purposes; No Teaching to Combine/Modify Components as a Matter of Law.

Concerning this, the USPTO has stated as follows:

Lebel et al teach a device comprising a body portion (6); at least one extensible finger (16) coupled to said body portion; at least one reservoir (84) in communication with said extensible finger; and a control circuitry (Paragraph [0140]) coupled to said body portion.

Lebel et al do not disclose, however, that the extensible finger is composed of a plurality of retractable segments which are configured to controllably telescopically extend from the body portion.

Douk teaches an implantable sheath catheter having a plurality of retractable segments (402, 403, 404) which are configured to controllably telescopically extend (via positioning wire 406: Figs. 4 and 5). Regarding claims 15 and 16, Douk further teaches that the plurality of retractable segments are configured to articulate at joints of adjacent segments (407-412, for example) and that the segments are hollow (Figs. 4 and 5). Further, regarding claims 66-68, the segments of Douk are configured to slidably collapse against adjacent segments (Fig. 5), impart length adjustability to the at least one extensible finger, and impart adjustability to the articulation of the at least one extensible finger (Figs. 4 and 5; the device can change in length, and the articulation of the segments changes based on whether the catheter is extended (Fig. 4), retracted (Fig. 5), or somewhere in between (not shown)).

At the time of the invention, it would have been obvious to one having ordinary skill in the art to substitute the extensible finger having a plurality of retractable segments of Douk for the extensible finger having a single segment of Lebel et al, because doing so would allow the physician to change the length of the catheter in vivo instead of having to alter the length of the catheter prior to insertion, and further it prevents the physician from having to remove the catheter in order to change its length after insertion.

Office Action, p. 5 (14 Oct 2009). [54]

First, Appellant agrees with the USPTO's statement that, "Lebel et al do not disclose, however, that the extensible finger is composed of a plurality of retractable segments which are configured to controllably telescopically extend from the body portion."

However, Appellant points out that, not only has the USPTO failed to adduce any objectively verifiable evidence sufficient to support the USPTO assertions regarding alleged teaching to modify/combine the cited references to meet the recitations of Independent Claim 1, there can be no such teaching as a matter of law. Specifically, shown following is that under the MPEP standard the USPTO's statements appear to be conclusory statements without evidentiary support, there can be no teaching to modify/combine the technology as suggested by the USPTO in that the proposed modification/combination changes the principle of operation of the technology, and there can be no teaching to modify/combine the technology as suggested by the USPTO in that the proposed modification/combination renders the technology unfit for one or more of its intended purposes.

(1) The USPTO Assertions Regarding A Teaching to Modify/Combine to Meet the Recitations of Independent Claim 1 Are Based on "Mere Conclusory Statements" Without Evidentiary Support

As explained above, the Supreme Court has stated that when an examiner attempts to establish unpatentability, the USPTO's "***analysis should be made explicit***" ... [***and*** that] rejections ... ***cannot be sustained by mere conclusory statements***; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.' *KSR v. Teleflex,* 550 U.S. 398; 127 S. Ct. 1727 at 1741 (citations omitted).

Concerning Claim 1, the USPTO has stated as follows:

[54] Appellant respectfully asserts that the USPTO has apparently not examined the recitations of Appellant's claims, but appears to have not addressed the express language of both Appellant's claims and the cited technical material. Accordingly, Appellant respectfully maintains that the USPTO has not established a *prima facie* case of the unpatentability of any pending claim for at least this reason. Notwithstanding the foregoing, Appellant demonstrates herein that even if the USPTO had followed the MPEP examination guidelines, no *prima facie* case of unpatentability would be extant.

At the time of the invention, it would have been obvious to one having ordinary skill in the art to substitute the extensible finger having a plurality of retractable segments of Douk for the extensible finger having a single segment of Lebel et al, because doing so would allow the physician to change the length of the catheter in vivo instead of having to alter the length of the catheter prior to insertion, and further it prevents the physician from having to remove the catheter in order to change its length after insertion.

Office Action, p. 5 (14 Oct 2009).

For reasons set forth above, Appellant respectfully submits that at least the underlined assertions set forth above are unsupported and erroneous, and appear to mischaracterize both the Lebel and Douk references. As such, this statement is neither evidence nor argument based upon evidence. Instead, the USPTO has attempted to support the present rejection based on a "mere conclusory statement." Appellant accordingly has requested without response that a rational underpinning for the present rejection be made explicit, or that the rejection be withdrawn.

(2) Modifications to Meet the Recitations of Independent Claim 1 Change the Principle of Operation of Components Being Modified; No Teaching to Modify/Combine Components as a Matter of Law.

With respect to this point, Appellant respectfully directs the Board to *MPEP* § 2143.01, Suggestion or Motivation to Modify the References, which states as follows (emphasis added):

> THE PROPOSED MODIFICATION CANNOT CHANGE THE PRINCIPLE OF OPERATION OF A REFERENCE
>
> If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (Claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers inserted in a resilient sealing member. The primary reference relied upon in a rejection based on a combination of references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing. Patentee taught the device required rigidity for operation, whereas the claimed invention required resiliency. The court reversed the rejection holding the "suggested combination of references would require a substantial reconstruction and redesign

of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." 270 F.2d at 813, 123 USPQ at 352.).

Appellant respectfully asserts that one reason for Lebel's lack of disclosure of "[b] **at least one extensible finger coupled to said body portion, the extensible finger being composed of a plurality of retractable segments, the plurality of retractable segments of the extensible finger configured to controllably telescopically extend from the body portion**" may be gleaned from principles of operation indicated in this recitation:

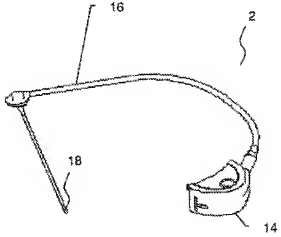

FIGURE 1B

The outer appearance of the implantable device 2 is depicted in two pieces in FIGS. 1a and 1b and includes housing 6 having a drug outlet port 8, and a refill port 12, a removable sideport 14 that mounts against the side of the housing 6 over outlet port 8, and **a catheter 16 having a distal end 18 and a proximal end that attaches to sideport 14**.

Lebel, Figure 1B and Paragraph 0137 (emphasis added).

Appellant respectfully points out that were one to incorporate "**at least one extensible finger coupled to said body portion, the extensible finger being composed of a plurality of retractable segments, the plurality of retractable segments of the extensible finger configured to controllably telescopically extend from the body portion**" of Claim 1 into the

structure of Lebel, Lebel would no longer provide "**a catheter 16 having a distal end 18 and a proximal end that attaches to sideport 14**." Thus, any modifications/combinations would change the principle of operation of Lebel for at least this reason.

As discussed above, one reason why such modified Lebel technology would be rendered unsatisfactory is that, at present, the USPTO has not yet provided any teaching of how to modify/combine the Lebel technology to provide "[b] **at least one extensible finger coupled to said body portion, the extensible finger being composed of a plurality of retractable segments, the plurality of retractable segments of the extensible finger configured to controllably telescopically extend from the body portion**" as recited in Independent Claim 1. Hence, there would need to be some type of reconstruction and/or redesign of Lebel.

As has been shown above, any modification of Lebel would require "substantial reconstruction and redesign of the elements shown in [...Lebel] as well as a change in the basic principle under which the [...Lebel] construction was designed to operate" in order to reach the recitations of Claim 1. Accordingly, insofar as that any modification to Lebel would likely require at least one additional and as-yet-hypothetical modification as explained above, under the MPEP standards set forth in block quote above, modification/combination "would change the principle of operation" of Lebel.

Insofar as that any modification/combination would itself require *substantial* hypothetical reconstruction and/or redesign to render Lebel capable of performing the intended purposes, under the MPEP guidelines as set forth above, the theory of operation of the technologies of Lebel will have been changed. Consequently, under the MPEP standards as set forth above there can be no teaching to modify/combine such reference to meet the recitations of Independent Claim 1 as a matter of law. Accordingly, for at least the foregoing reasons, Appellant respectfully asks the Board to reverse the USPTO's rejections of Independent Claim 1 as being unpatentable, and hold Independent Claim 1 allowable and to issue a Notice of Allowance of same.

(3) Modifications to Meet the Recitations of Independent Claim 1 Render Components Being Modified Unsatisfactory for their Intended Purposes; No Teaching to Modify/Combine Components as a Matter of Law.

Furthermore, "if proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." With respect to this point, Appellant respectfully directs the Board to *MPEP* § 2143.01, Suggestion or Motivation to Modify the References, which states as follows (emphasis added):

> THE PROPOSED MODIFICATION CANNOT RENDER THE PRIOR ART UNSATISFACTORY FOR ITS INTENDED PURPOSE
>
> If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) (Claimed device was a blood filter assembly for use during medical procedures wherein both the inlet and outlet for the blood were located at the bottom end of the filter assembly, and wherein a gas vent was present at the top of the filter assembly. The prior art reference taught a liquid strainer for removing dirt and water from gasoline and other light oils wherein the inlet and outlet were at the top of the device, and wherein a pet-cock (stopcock) was located at the bottom of the device for periodically removing the collected dirt and water. The reference further taught that the separation is assisted by gravity. The Board concluded the claims were *prima facie* obvious, reasoning that it would have been obvious to turn the reference device upside down. The court reversed, finding that if the prior art device was turned upside down it would be inoperable for its intended purpose because the gasoline to be filtered would be trapped at the top, the water and heavier oils sought to be separated would flow out of the outlet instead of the purified gasoline, and the screen would become clogged.).

Appellant again points out that the USPTO has provided no evidence to modify/combine the cited technical materials to reach the recitations of Independent Claim 1. Even assuming, arguendo, that the USPTO had produced an as-yet-unknown objective teaching of how to modify/combine the structure of Lebel with the technology of Douk to create "**at least one extensible finger coupled to said body portion, the extensible finger being composed of a plurality of retractable segments, the plurality of retractable segments of the extensible finger configured to controllably telescopically extend from the body portion**" (as set forth

in Independent Claim 1) such a modification/combination would apparently render the technology of Lebel unsatisfactory for one or more of its intended purposes.

Lebel recites:

> The implantable device and external communication device are preferably also designed and are controlled to meet certain longevity requirements in combination with the desired functional requirements. **It is desired that the implantable device remain operational within the body of a patient for a period of about five years or longer, more preferably a period of about seven years or longer, and most preferably a period of about 9 years or longer**.

Lebel, Paragraph 0201 (emphasis added). It is unclear, at best, how this purpose could be served in conjunction with "**Grip portion 101 is a handle for the clinician to grasp and manipulate positioning wire 106** ... **Alternatively, grip portion 101 may be eliminated entirely, and the clinician will simply grasp positioning wire 106 directly**" as recited by Douk. Thus, for at least this reason, the suggested modifications/combinations would render the technology of Lebel unsatisfactory for one or more of its intended purposes. There can thus be no teaching to modify/combine such references to meet the recitations of Independent Claim 1 as a matter of law. Accordingly, for at least the foregoing reasons, Appellant respectfully asks the Board to reverse the USPTO's rejections of Independent Claim 1 as being unpatentable, and hold Independent Claim 1 allowable and to issue a Notice of Allowance of same.

5. Labbe and Douk Do Not Show/Suggest Recitations of Independent Claim 1

a) Modifications/Combinations to Meet the Recitations of Independent Claim 1 are Conclusory Statements; Change the Principle of Operation of Components of Cited References; and Render Cited References Unfit for Intended Purposes; No Teaching to Combine/Modify Components as a Matter of Law.

Concerning this, the USPTO has stated as follows:

> Labbe et al disclose a device comprising a body portion (3); at least one extensible finger (2) coupled to said body portion; at least one reservoir (12) in communication with said extensible finger; and a control circuitry (Figure 4) coupled to said body portion.

Labbe et al do not disclose, however, that the extensible finger is composed of a plurality of retractable segments which are configured to controllably telescopically extend from the body portion.

Douk teaches an implantable sheath catheter having a plurality of retractable segments (402, 403, 404) which are configured to controllably telescopically extend (via positioning wire 406; Figs. 4 and 5). Regarding claims 15 and 16, Douk further teaches that the plurality of retractable segments are configured to articulate at joints of adjacent segments (407-412, for example) and that the segments are hollow (Figs. 4 and 5). Further, regarding claims 66-68, the segments of Douk are configured to slidably collapse against adjacent segments (Fig. 5), impart length adjustability to the at least one extensible finger, and impart adjustability to the articulation of the at least one extensible finger (Figs. 4 and 5; the device can change in length, and the articulation of the segments changes based on whether the catheter is extended (Fig. 4), retracted (Fig. 5), or somewhere in between (not shown)).

At the time of the invention, it would have been obvious to one having ordinary skill in the art to substitute the extensible finger having a plurality of retractable segments of Douk for the extensible finger having a single segment of Labbe et al, because doing so would allow the physician to change the length of the catheter in vivo instead of having to alter the length of the catheter prior to insertion, and further it prevents the physician from having to remove the catheter in order to change its length after insertion.

Office Action, p. 6 (14 Oct 2009). [55]

Appellant agrees with the USPTO's statement that, "Labbe et al do not disclose, however, that the extensible finger is composed of a plurality of retractable segments which are configured to controllably telescopically extend from the body portion."

However, Appellant points out that, not only has the USPTO failed to adduce any objectively verifiable evidence sufficient to support the USPTO assertions regarding alleged teaching to modify/combine the cited references to meet the recitations of Independent Claim 1,

[55] Appellant respectfully asserts that the USPTO has apparently not examined the recitations of Appellant's claims, but appears to have not addressed the express language of both Appellant's claims and the cited technical material. Accordingly, Appellant respectfully maintains that the USPTO has not established a *prima facie* case of the unpatentability of any pending claim for at least this reason. Notwithstanding the foregoing, Appellant demonstrates herein that even if the USPTO had followed the MPEP examination guidelines, no *prima facie* case of unpatentability would be extant.

there can be no such teaching as a matter of law. Specifically, shown following is that under the MPEP standard the USPTO's statements appear to be conclusory statements without evidentiary support, there can be no teaching to modify/combine the technology as suggested by the USPTO in that the proposed modification/combination changes the principle of operation of the technology, and there can be no teaching to modify/combine the technology as suggested by the USPTO in that the proposed modification/combination renders the technology unfit for one or more of its intended purposes.

(1) The USPTO Assertions Regarding A Teaching to Modify/Combine to Meet the Recitations of Independent Claim 1 Are Based on "Mere Conclusory Statements" Without Evidentiary Support

As explained above, the Supreme Court has stated that when an examiner attempts to establish unpatentability, the USPTO's "***analysis should be made explicit***" ... [***and*** that] rejections ... ***cannot be sustained by mere conclusory statements***; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.' *KSR v. Teleflex*, 550 U.S. 398; 127 S. Ct. 1727 at 1741 (citations omitted).

Concerning Claim 1, the USPTO has stated as follows:

> **At the time of the invention, it would have been obvious to one having ordinary skill in the art to substitute the extensible finger having a plurality of retractable segments of Douk for the extensible finger having a single segment of Labbe et al, because doing so would allow the physician to change the length of the catheter in vivo instead of having to alter the length of the catheter prior to insertion, and further it prevents the physician from having to remove the catheter in order to change its length after insertion.**

Office Action, p. 6 (14 Oct 2009).[56]

[56] Appellant respectfully asserts that the USPTO has apparently not examined the recitations of Appellant's claims, but appears to have not addressed the express language of both Appellant's claims and the cited technical material. Accordingly, Appellant respectfully maintains that the USPTO has not established a *prima facie* case of the unpatentability of any pending claim for at least this reason. Notwithstanding the foregoing, Appellant demonstrates herein that even if the USPTO had followed the MPEP examination guidelines, no *prima facie* case of unpatentability would be extant.

For reasons set forth above, Appellant respectfully submits that at least the underlined assertions set forth above are unsupported and erroneous, and appear to mischaracterize both the Labbe and Douk references. As such, this statement is neither evidence nor argument based upon evidence. Instead, the USPTO has attempted to support the present rejection based on a "mere conclusory statement." Appellant accordingly has requested without response that a rational underpinning for the present rejection be made explicit, or that the rejection be withdrawn.

(2) Modifications to Meet the Recitations of Independent Claim 1 Change the Principle of Operation of Components Being Modified; No Teaching to Modify/Combine Components as a Matter of Law.

With respect to this point, Appellant respectfully directs the Board to *MPEP* § 2143.01, Suggestion or Motivation to Modify the References, which states as follows (emphasis added):

> THE PROPOSED MODIFICATION CANNOT CHANGE THE PRINCIPLE OF OPERATION OF A REFERENCE
>
> If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (Claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers inserted in a resilient sealing member. The primary reference relied upon in a rejection based on a combination of references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing. Patentee taught the device required rigidity for operation, whereas the claimed invention required resiliency. The court reversed the rejection holding the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." 270 F.2d at 813, 123 USPQ at 352.).

Appellant respectfully asserts that one reason for Labbe's lack of disclosure of "[b] **at least one extensible finger coupled to said body portion, the extensible finger being composed of a plurality of retractable segments, the plurality of retractable segments of the**

extensible finger configured to controllably telescopically extend from the body portion" may be gleaned from principles of operation indicated in this recitation:

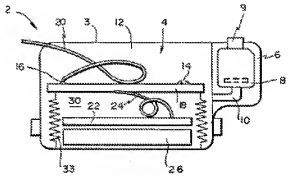

FIG. 2

Labbe, Figure 2, Col. 3, Lines 3-33 (emphasis added).

Appellant respectfully points out that were one to incorporate "**at least one extensible finger coupled to said body portion, the extensible finger being composed of a plurality of retractable segments, the plurality of retractable segments of the extensible finger configured to controllably telescopically extend from the body portion**" of Claim 1 into the structure of Labbe, Labbe would no longer provide "**catheter 20**" as illustrated above in Figure 2. Thus, any modifications/combinations would change the principle of operation of Labbe for at least this reason.

As discussed above, one reason why such modified Labbe technology would be rendered unsatisfactory is that, at present, the USPTO has not yet provided any teaching of how to modify/combine the Labbe technology to provide "[b] **at least one extensible finger coupled to said body portion, the extensible finger being composed of a plurality of retractable segments, the plurality of retractable segments of the extensible finger configured to controllably telescopically extend from the body portion**" as recited in Independent Claim 1. Hence, there would need to be some type of reconstruction and/or redesign of Labbe.

As has been shown above, any modification of Labbe would require "substantial reconstruction and redesign of the elements shown in [...Labbe] as well as a change in the basic principle under which the [...Labbe] construction was designed to operate" in order to reach the recitations of Claim 1. Accordingly, insofar as that any modification to Labbe would likely require at least one additional and as-yet-hypothetical modification as explained above, under the MPEP standards set forth in block quote above, modification/combination "would change the principle of operation" of Labbe.

Insofar as that any modification/combination would itself require *substantial* hypothetical reconstruction and/or redesign to render Labbe capable of performing the intended purposes, under the MPEP guidelines as set forth above, the theory of operation of the technologies of Labbe will have been changed. Consequently, under the MPEP standards as set forth above there can be no teaching to modify/combine such reference to meet the recitations of Independent Claim 1 as a matter of law. Accordingly, for at least the foregoing reasons, Appellant respectfully asks the Board to reverse the USPTO's rejections of Independent Claim 1 as being unpatentable, and hold Independent Claim 1 allowable and to issue a Notice of Allowance of same.

(3) Modifications to Meet the Recitations of Independent Claim 1 Render Components Being Modified Unsatisfactory for their Intended Purposes; No Teaching to Modify/Combine Components as a Matter of Law.

Furthermore, "if proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." With respect to this point, Appellant respectfully directs the Board to *MPEP* § 2143.01, Suggestion or Motivation to Modify the References, which states as follows (emphasis added):

> THE PROPOSED MODIFICATION CANNOT RENDER THE PRIOR ART UNSATISFACTORY FOR ITS INTENDED PURPOSE
>
> If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125

(Fed. Cir. 1984) (Claimed device was a blood filter assembly for use during medical procedures wherein both the inlet and outlet for the blood were located at the bottom end of the filter assembly, and wherein a gas vent was present at the top of the filter assembly. The prior art reference taught a liquid strainer for removing dirt and water from gasoline and other light oils wherein the inlet and outlet were at the top of the device, and wherein a pet-cock (stopcock) was located at the bottom of the device for periodically removing the collected dirt and water. The reference further taught that the separation is assisted by gravity. The Board concluded the claims were *prima facie* obvious, reasoning that it would have been obvious to turn the reference device upside down. The court reversed, finding that if the prior art device was turned upside down it would be inoperable for its intended purpose because the gasoline to be filtered would be trapped at the top, the water and heavier oils sought to be separated would flow out of the outlet instead of the purified gasoline, and the screen would become clogged.).

Appellant again points out that the USPTO has provided no evidence to modify/combine the cited technical materials to reach the recitations of Independent Claim 1. Even assuming, *arguendo,* that the USPTO had produced an as-yet-unknown objective teaching of how to modify/combine the structure of Labbe with the technology of Douk to create "**at least one extensible finger coupled to said body portion, the extensible finger being composed of a plurality of retractable segments, the plurality of retractable segments of the extensible finger configured to controllably telescopically extend from the body portion**" (as set forth in Independent Claim 1) such a modification/combination would apparently render the technology of Labbe unsatisfactory for one or more of its intended purposes.

Labbe recites, "Referring now to the drawings, there is shown **an implantable dispenser 2** for use in a drug delivery system where **the dispenser is implanted into the body of a human being** and is operative to dispense into the body suitable quantities of a drug at intervals **under control of a circuit within the dispenser** and as required **under external control by means of a receiver/transmitter arrangement**." *Labbe*, Col. 2, Lines 53-60 (emphasis added). It is unclear, at best, how this purpose could be served in conjunction with "**Grip portion 101 is a handle for the clinician to grasp and manipulate positioning wire 106** ... **Alternatively, grip portion 101 may be eliminated entirely, and the clinician will simply grasp positioning wire 106 directly**" as recited by Douk. Thus, for at least this reason, the suggested modifications/combinations would render the technology of Labbe unsatisfactory for one or more of its intended purposes. There can thus be no teaching to modify/combine such references to meet the recitations of Independent Claim 1 as a matter of law. Accordingly, for at least the

foregoing reasons, Appellant respectfully asks the Board to reverse the USPTO's rejections of Independent Claim 1 as being unpatentable, and hold Independent Claim 1 allowable and to issue a Notice of Allowance of same.

6. Dependent Claims 2-34 and 66-68 Patentable for at Least Reasons of Dependency from Independent Claim 1

Claims 2-34 and 66-68[57] depend either directly or indirectly from Independent Claim 1. "A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers." *See* 35 U.S.C. § 112 paragraph 4. Consequently, Dependent Claims 2-34 and 66-68 are patentable for at least the reasons why Independent Claim 1 is patentable. Accordingly, for at least the foregoing reasons, Appellant respectfully asks the Board to reverse the USPTO's rejections of Dependent Claims 2-34 and 66-68 as being unpatentable, and hold Dependent Claims 2-34 and 66-68 allowable and to issue a Notice of Allowance of same.

7. Dependent Claim 24 is Independently Patentable

Independent Claim 1 recites as follows:

1. A device for perfusion management, comprising:

a body portion;

at least one extensible finger coupled to said body portion, the extensible finger being composed of a plurality of retractable segments, the plurality of retractable segments of the extensible finger configured to controllably telescopically extend from the body portion;

[57] In relation to these dependent claims, the USPTO has provided no objectively verifiable evidence, nor argument based on objectively verifiable evidence, in support of its assertions regarding what the USPTO-cited material "discloses." Insofar as this alleged disclosure is not literally recited in such material, Appellant respectfully asserts that the Examiner must have relied on "personal knowledge" or taken improper "official notice" of one or more factors to reach each of these assertions. Applicant accordingly has requested without response an appropriate affidavit or declaration in support of any of these rejections that are to be maintained, including any considerations purported to reflect what is "well known in the art." *See, e.g.*, 37 C.F.R. 1.104(d)(2).

at least one reservoir in communication with said extensible finger; and

a control circuitry coupled to said extensible finger, and/or said body portion.

Dependent Claim 24 recites as follows:

24. The device for perfusion management according to claim 1, wherein said control circuitry is operative to guide said extensible finger.

Concerning Claim 24, the USPTO has recently stated as follows:

Davison et al also disclose a device for evacuating a target or cauterizing (102, 103, 104), and that **the control circuitry is coupled to guide or control the extensible finger (10).**

Office Action, p. 8 (14 Oct 2009) (emphasis added).[58]

As set forth above, Dependent Claim 24 recites as follows: "wherein said **control circuitry is operative to guide said extensible finger**."

It appears to Appellant that the USPTO has mapped "wherein said **control circuitry is operative to guide said extensible finger**" onto "control circuitry is coupled to **guide or control** the extensible finger (10)":

[58] Appellant respectfully asserts that the USPTO has apparently not examined the recitations of Appellant's claims, but appears to have not addressed the express language of both Appellant's claims and the cited technical material. Accordingly, Appellant respectfully maintains that the USPTO has not established a *prima facie* case of the unpatentability of any pending claim for at least this reason. Notwithstanding the foregoing, Appellant demonstrates herein that even if the USPTO had followed the MPEP examination guidelines, no *prima facie* case of unpatentability would be extant.

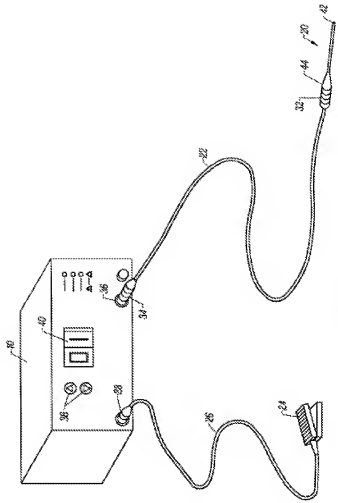

FIG. 1

Davison, Figure 1.

Appellant notes that the USPTO has not explained how it reaches such mappings under the broadest reasonable interpretation framework as is the USPTO's burden (e.g., such as by examples drawn from Appellant's claims or detailed description),[59] and furthermore, Appellant

[59] Irrespective of a desire to be cooperative, the ability of any patent practitioner to help the Examiner fulfill this burden on the record is tightly curtailed by pre- and post-issuance legal standards and by various ethical duties in tension. *See, e.g.*, 37 C.F.R. § 10.83 ("A practitioner should represent a client zealously within the bounds of the law."); 37 C.F.R. § 10.84 ("[A] practitioner shall not intentionally … [p]rejudice or damage a client during the course of a professional relationship, except as required under this [ethics] part."); and 37 C.F.R. § 10.76 ("A practitioner should represent a client competently."). For these and other reasons, this document notes instances in which the USPTO did not follow the prescribed rules rather than seeking to interpret claims and/or to adduce evidence on the USPTO's behalf.

points out that this mapping does not address "wherein said **control circuitry is operative to guide said extensible finger**."

In view of the foregoing, Appellant points out that although Dependent Claim 24 has been quoted in the present rejection, several claim terms have not been addressed in its analysis. Because the USPTO-cited material fails to recite at least the foregoing bolded recitations of Dependent Claim 24,[60] under the MPEP guidelines as set forth above, such material does not establish a *prima facie* case of the unpatentability of Dependent Claim 24. Accordingly, for at least the foregoing reasons, Appellant respectfully asks the Board to reverse the USPTO's rejections of Dependent Claim 24 as being unpatentable, and hold Dependent Claim 24 allowable and to issue a Notice of Allowance of same.

Moreover, Appellant respectfully points out that Appellant has reviewed the Davison reference identified by the USPTO, and so far as Appellant can discern, the Davison reference does not recite "wherein said **control circuitry is operative to guide said extensible finger**" as recited in Appellant's Dependent Claim 24.[61] Rather, the portions of Davison cited by the USPTO actually recite as follows:

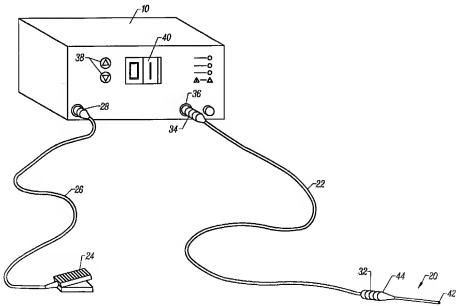

FIG. 1

[60] Although Dependent Claim 24 has been quoted in the present rejection, several claim terms have not been addressed in its analysis, as shown below.

[61] Nor does Davison recite as the USPTO alleges, for that matter; Appellant again points out that, in derogation of the MPEP guidelines, the USPTO has not addressed the language of Appellant's Dependent Claim 24.

Power supply 10 has an operator controllable voltage level adjustment 38 to change the applied voltage level, which is 10 observable at a voltage level display 40. Power supply 10 also includes one or more foot pedals 24 and a cable 26 which is removably coupled to a receptacle 30 with a cable connector 28. The foot pedal 24 may also include a second pedal (not shown) for remotely adjusting the energy level applied to electrode terminals 104, and a third pedal (also not shown) for switching between an ablation mode and a coagulation mode.

Handle 204 typically comprises a plastic material that is easily molded into a suitable shape for handling by the surgeon.

Davison, Figure 1 and Col. 17, Lines 40-49, Col. 18, Lines 4-6 (emphasis added).

The USPTO is characterizing Davison to "teach" at least some of the text of Dependent Claim 24, but does not support its characterization with objectively verifiable evidence. The USPTO has therefore not met its burden to establish a *prima facie* case of unpatentability for Dependent Claim 24. What a reference "teaches" is a question of fact.[62,63,64] Conclusory statements that a reference "teaches" something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such "teachings" unless they are supported by objective evidence. *See In re McNeil-PPC,* 2008-1546 (Fed. Cir. July 31, 2009);[65] *In re Lee,* 277 F.3d

[62] *See Rapoport v. Dement,* 254 F.3d 1053, 1060 (Fed. Cir. 2001) ("What a reference teaches is a question of fact... Therefore, we review the Board's characterization of the disclosure in the FPR Publication for substantial evidence.") (emphasis added).

[63] *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO and holding when the PTO presented no evidence to cure *prima facie* differences between patent claim and Examiner assertions regarding what the allegedly invalidating prior art "taught")

[64] Anticipation, as well as what a reference teaches, is a question of fact. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002).

[65] In *McNeil,* the Examiner had rejected claims reciting a tampon having "a generally cylindrical compressed, solid fibre core" and ribs "compressed less than the fiber core" in view of a Japanese patent application ("Sasaki"). McNeil appealed to the Board of Patent Appeals and Interferences, which "specifically found that 'Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward.'" *See id.,* 2008-1546, slip op. 1, 3 (Fed. Cir. July 31, 2009). In light of this and its finding that of each rib of Sasaki being "compressed less than the fiber core," the Board affirmed the rejections. Insofar that the Sasaki reference did not directly disclose/recite as alleged by the Board, and since the Board did not supply evidence supporting its statement that "Sasaki reasonably appears to depict a tampon having a generally cylindrical absorbent portion with a generally cylindrical compressed solid fiber core from which longitudinal ribs extend radially outward," the Federal Circuit reversed the rejection for lack of "substantial evidentiary support," stating as follows:

1338 (Fed. Cir. 2002);[66] *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000) ("Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto. … Broad conclusory statements standing alone are not "evidence.").[67] Even if the PTO personnel were to seek to support their characterizations with an expert witness affidavit, the law is that conclusory statements by an expert that a reference "teaches" something beyond its bare recitations/direct disclosure do not constitute ANY evidence of such "teachings" unless they are

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> There is not substantial evidence, indeed, no evidence, that Sasaki discloses ribs "compressed less than the fiber core" or "a generally cylindrical compressed, solid fibre core." ... Just as the Sasaki figures do not indicate the relative compression of the different portions of the tampon, the Sasaki figures completely lack any indication of the relative coarseness of different portions. ... Lastly, turning to the issue of spacing of the ribs, Figure 8 shows a space between the bottommost ribs, and there is arguably some space shown between other ribs. However, because it is neither clear that Sasaki discloses a core nor which portions of Sasaki's tampon the Board considered to be the ribs and which the Board considered to be the core, we cannot say that substantial evidence supports the Board's determination that Sasaki discloses ribs separated from each other "at the proximal end by an amount greater than" than at "the distal end."

See id., 2008-1546, slip op. 1, 10-11 (Fed. Cir. July 31, 2009).

[66] In *Lee,* the USPTO argued that, to the "common sense of a person of ordinary skill in the art," it was obvious that one could combine a prior patent for an on-screen television menu with an on-screen picture-quality adjustment for a video game played on a television illustrated in the game's handbook. The Federal Circuit ruled that obviousness must be based on "objective evidence of record." Finding no specific published suggestion in the record, the Federal Circuit ruled the invention patentable. *See id.,* 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (describing the BPAI's obligation to develop an evidentiary basis for its factual findings to allow for meaningful judicial review under the substantial evidence standard).

[67] In *Kotzab*, the Federal Circuit reversed the BPAI as follows:

> The Examiner cites Evans for teaching that "one *system* constructed and operated according to the invention may be used to control a number of valves." Evans application, p. 19, ll. 6-8 (emphasis added). In view of this disclosure only, the Examiner concluded that Evans teaches the use of one *sensor* to control a number of valves. This conclusion must necessarily rest on the unstated premise by the Examiner that "one system" is equal to "one sensor."
>
> But the Board's decision, adopting the Examiner's premise, lacks the necessary substantial evidence to support a rejection of Kotzab's claims. Specifically, there is not substantial evidence to show that "one system" is the same thing as "one sensor." The words "sensor" and "probe" are used throughout Evans to refer to the device that measures the mold temperature. … Evans clearly never uses the term "system" as a substitute for the simple temperature measuring device it calls "sensor." And, the Board made no reference to any evidence in the record that would equate "one system" with "one sensor."
>
> As mentioned previously, more than a mere scintilla of evidence is necessary to support the Board's implicit conclusion that "one system" is equal to "one sensor." Based on the entirety of Evans' disclosure, we cannot say that there is such relevant evidence as a reasonable mind might accept as adequate to support the conclusion that "one system" means "one sensor."

See id., 217 F.3d 1365, 1370-71 (Fed. Cir. 2000) (underline added).

supported by objective documentary evidence.[68] Thus, when a party to a matter asserts that a reference "teaches" something beyond its bare recitations/direct disclosure, and that factual assertion is challenged by an opposite party, the law requires that the asserting party provide objective evidentiary support to "close the gap" between what the reference recites and the what the asserting party *alleges* the reference teaches; in the absence of such evidence, there should be no finding of fact in favor of the asserted teaching.[69,70,71,72] For each instance below in which the USPTO has made an unsupported characterization, Appellant accordingly has requested without response that the USPTO either (1) withdraw the corresponding claim rejection or (2) provide an affidavit setting forth objectively verifiable evidence sufficient to "close the gap" between the characterization and what the reference actually recites.

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[68] *See Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1473 (Fed. Cir. 1997) ("The district court's holding misapprehends the rigors of anticipation. For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art... **Although this disclosure requirement presupposes the knowledge of one skilled in the art of the claimed invention, that presumed knowledge does not grant a license to read into the prior art reference teachings that are not there. An expert's conclusory testimony, unsupported by the documentary evidence, cannot supplant the requirement of anticipatory disclosure in the prior art reference itself.**") (emphasis added); *see also Genzyme Corp. v. Atrium Med. Corp.*, 315 F. Supp. 2d 552, 563 (D. Del. 2004) ("For a patent to be anticipated, every element of a patent claim must appear in a single reference. **Other references and opinion may be used to reveal what the reference would have meant to those skilled in the art at the time of the invention**.... **For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art. Presumed knowledge of one skilled in the art does not allow an expert to read into the reference elements that are not there.**") (emphasis added)

[69] *See Rapoport v. Dement* 254 f. 3rd 1053, 1060 (Fed. Cir. 2001) . In *Rapoport,* the Federal Circuit affirmed the Board's holding that a publication did not anticipate a claim, reasoning as follows (emphasis added):

> Having construed the disputed term in the interference count and affirmed the Board's interpretation, we can properly address the merits of Rapoport's anticipation argument. The Board found that the disclosure of the FPR Publication was limited to treatment of anxiety in patients suffering from sleep apnea with buspirone, and did not address treatment of the underlying sleep apnea disorder. What a reference **teaches** is a question of fact.... There is no disclosure in the FPR Publication of tests in which buspirone is administered to patients suffering from sleep apnea with the intent to cure the underlying condition.... The Board also correctly found that the FPR Publication does not show administering buspirone in any specific amounts to patients suffering from sleep apnea.... We note that there is no mention in the FRP Publication of administering buspirone to a patient at bedtime.... Therefore, for all the reasons stated above, we find that the Board's conclusion that the FPR Publication does not disclose administration of buspirone to patients suffering from sleep apnea to treat sleep apnea is supported by substantial evidence.

[70] *See In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (reversing the PTO's holding that a gene was "prima facie obvious over its corresponding protein" in the cited reference, absent any evidence of a one-to-one correspondence).

[71] *See In re McNeil-PPC*, 2008-1546 (Fed. Cir. July 31, 2009).

[72] *See In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

As can be seen from the foregoing, for example, the USPTO-identified portions of Davison do *not recite* the text of Dependent Claim 24: "wherein said **control circuitry is operative to guide said extensible finger.**"

Instead, Davison recites in reference to Figure 1 above that:

> **Handle 204 typically comprises a plastic material that is easily molded into a suitable shape for handling by the surgeon**.
>
> *Davison*, Col. 18, Lines 4-6 (emphasis added).

Appellant has shown by direct quotations that Dependent Claim 24 and the Davison reference are very different on their faces. *See supra* (quotation of Claim 24 and its parent claim and quotation of Davison). Insofar that Appellant has shown that *"at first sight; on the first appearance; on the face of it; so far as can be judged from the first disclosure"* the USPTO-cited art is very different from Claim 24, and Appellant has noted that the USPTO has not cited to any objectively verifiable evidence/argument based on same sufficient to remedy such *prima facie* differences, the USPTO-cited technical material does not establish a *prima facie* case of the unpatentability of Claim 24 either under the MPEP or under controlling legal standards. *See supra.*

Accordingly, insofar as that Davison does not recite the text of Dependent Claim 24, and insofar as that the USPTO has provided no objectively verifiable evidence, or argument based on objectively verifiable evidence, as to how Davison could be modified/combined to teach Dependent Claim 24, Appellant respectfully points out that under the MPEP guidelines as set forth above, the USPTO-cited technical material does not a establish a *prima facie* case of the unpatentability of Dependent Claim 24 for at least these reasons. Accordingly, for at least the foregoing reasons, Appellant respectfully asks the Board to reverse the USPTO's rejections of Dependent Claim 24 as being unpatentable, and hold Dependent Claim 24 allowable and to issue a Notice of Allowance of same.

In addition and/or in the alternative to the foregoing, Appellant additionally points out that, not only has the USPTO failed to adduce any objectively verifiable evidence sufficient to support the USPTO assertions regarding alleged teaching to modify/combine Davison to meet the recitations of Dependent Claim 24, there can be no such teaching as a matter of law. Specifically, shown following is that under the MPEP standards there can be no teaching to

modify/combine the technology of Davison in that the proposed modification/combination changes the principle of operation of the technology.

With respect to this point, Appellant respectfully directs the Board to *MPEP* § 2143.01, Suggestion or Motivation to Modify the References, which states as follows (emphasis added):

> THE PROPOSED MODIFICATION CANNOT CHANGE THE PRINCIPLE OF OPERATION OF A REFERENCE
>
> If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (Claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers inserted in a resilient sealing member. The primary reference relied upon in a rejection based on a combination of references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing. Patentee taught the device required rigidity for operation, whereas the claimed invention required resiliency. The court reversed the rejection holding the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." 270 F.2d at 813, 123 USPQ at 352.).

Appellant respectfully asserts that one reason for Davison's lack of disclosure of "wherein said **control circuitry is operative to guide said extensible finger**" may be gleaned from principles of operation indicated in this recitation:

> **Handle 204 typically comprises a plastic material that is easily molded into a suitable shape for handling by the surgeon.**
>
> *Davison*, Col. 18, Lines 4-6 (emphasis added).

Appellant respectfully points out that were one to incorporate "wherein said **control circuitry is operative to guide said extensible finger**" of Claim 24 into the structure of Davison, Davison would no longer provide "**Handle 204 typically comprises a plastic material that is easily molded into a suitable shape for handling by the surgeon.**" Thus, any modifications/combinations would change the principle of operation of Davison for at least this reason.

As discussed above, one reason why such modified Davison technology would be rendered unsatisfactory is that, at present, the USPTO has not yet provided any teaching of how to modify/combine the Davison technology to provide "wherein said **control circuitry is operative to guide said extensible finger**" as recited in Dependent Claim 24. Hence, there would need to be some type of reconstruction and/or redesign of Davison.

As has been shown above, any modification of Davison would require "substantial reconstruction and redesign of the elements shown in [... Davison] as well as a change in the basic principle under which the [... Davison] construction was designed to operate" in order to reach the recitations of Claim 24. Accordingly, insofar as that any modification to Davison would likely require at least one additional and as-yet-hypothetical modification as explained above, under the MPEP standards set forth in block quote above, modification/combination "would change the principle of operation" of Davison.

Insofar as that any modification/combination would itself require *substantial* hypothetical reconstruction and/or redesign to render Davison capable of performing the intended purposes, under the MPEP guidelines as set forth above, the theory of operation of the technologies of Davison will have been changed. Consequently, under the MPEP standards as set forth above there can be no teaching to modify/combine such reference to meet the recitations of Dependent Claim 24 as a matter of law. Accordingly, for at least the foregoing reasons, Appellant respectfully asks the Board to reverse the USPTO's rejections of Dependent Claim 24 as being unpatentable, and hold Dependent Claim 24 allowable and to issue a Notice of Allowance of same.

X. CONCLUSION

Appellant may have during the course of prosecution cancelled and/or amended one or more claims. Appellant notes that any such cancellations and/or amendments will have transpired (i) prior to issuance and (ii) in the context of the rules that govern claim interpretation during prosecution before the United States Patent and Trademark Office (PTO). Appellant notes that the rules that govern claim interpretation during prosecution form a radically different context than the rules that govern claim interpretation subsequent to a patent issuing. Accordingly, Appellant respectfully submits that any cancellations and/or amendments during the course of prosecution should be held to be tangential to and/or unrelated to patentability in the event that such cancellations and/or amendments are viewed in a post-issuance context under post-issuance claim interpretation rules.

Insofar as that the Appellant may have during the course of prosecution cancelled/amended claims sufficient to obtain a Notice of Allowability of all claims pending, Appellant may not have during the course of prosecution explicitly addressed all rejections and/or statements in Office Actions. The fact that rejections and/or statements may not be explicitly addressed during the course of prosecution should NOT be taken as an admission of any sort, and Appellant hereby reserves any and all rights to contest such rejections and/or statements at a later time. Specifically, no waiver (legal, factual, or otherwise), implicit or explicit, is hereby intended (e.g., with respect to any facts of which the USPTO took Official Notice, and/or for which the USPTO has supplied no objective showing, Appellant hereby contests those facts and requests express documentary proof of such facts at such time at which such facts may become relevant). For example, although not expressly set forth during the course of prosecution, Appellant continues to assert all points of (e.g. caused by, resulting from, responsive to, etc.) any previous Office Action, and no waiver (legal, factual, or otherwise), implicit or explicit, is hereby intended. Specifically, insofar as that Appellant does not consider the cancelled/unamended claims to be unpatentable, Appellant hereby gives notice that it may intend to file and/or has filed a continuing application in order prosecute such cancelled/unamended claims.

With respect to any cancelled claims, such cancelled claims were and continue to be a

part of the original and/or present patent application(s). Appellant hereby reserves all rights to present any cancelled claim or claims for examination at a later time in this or another application. Appellant hereby gives public notice that any cancelled claims are still to be considered as present in all related patent application(s) (e.g. the original and/or present patent application) for all appropriate purposes (e.g., written description and/or enablement). Appellant does NOT intend to dedicate the subject matter of any cancelled claims to the public.

Should this case go to appeal, Appellant reserves the right to submit argument, rebuttal evidence, or legal authority in the instance the Board of Patent Appeals and Interferences finds that the USPTO has met its burden in establishing a *prima facie* case of unpatentability of the various appealed claims. Appellant further reserves the right to submit argument, rebuttal evidence, or legal authority if new claim interpretations or definitional citations are raised on appeal. The fact that argument, rebuttal evidence, or legal authority may not have been explicitly discussed during the course of prosecution should NOT be taken as an admission or waiver of any sort, and Appellant hereby reserves any and all rights to discuss (e.g. make explicit, produce, or explain) such rebuttal evidence at a later time.

Respectfully submitted,

/James J. Ruttler, 56,919/ __April 1, 2010__

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APPENDIX A. APPENDIX OF CLAIMS INVOLVED IN THE APPEAL

1. (PREVIOUSLY PRESENTED) A device for perfusion management, comprising:

a body portion;

at least one extensible finger coupled to said body portion, the extensible finger being composed of a plurality of retractable segments, the plurality of retractable segments of the extensible finger configured to controllably telescopically extend from the body portion;

at least one reservoir in communication with said extensible finger; and

a control circuitry coupled to said extensible finger, and/or said body portion.

2. (PREVIOUSLY PRESENTED) The device for perfusion management according to claim 1, further comprising a device for data gathering, data processing, data storage, and/or data transmission.

3. (PREVIOUSLY PRESENTED) The device for perfusion management according to claim 1, further comprising an imager, a pressure sensor, a temperature sensor, a chemical sensor, a gas sensor, an electrolyte sensor, a composition sensor, a concentration sensor, and/or a flow sensor coupled to said extensible finger.

4. (PREVIOUSLY PRESENTED) The device for perfusion management according to claim 1, further comprising a pump, and/or a source of pressure coupled to said extensible finger.

5. (PREVIOUSLY PRESENTED) The device for perfusion management according to claim 1, further comprising a motor and/or an actuator coupled to said extensible finger.

6. (PREVIOUSLY PRESENTED) The device for perfusion management according to claim 1, further comprising a wireless data transmitter, coupled to said extensible finger and/or said control circuitry.

7. (PREVIOUSLY PRESENTED) The device for perfusion management according to claim 1, further comprising a wireless data receiver, and/or a wireless data controller coupled to said extensible finger and/or said control circuit.

8. (PREVIOUSLY PRESENTED) The device according to claim 1, wherein said at least one extensible finger is coupled to a source of a chemical, a chemical compound, a protein, a lipoprotein, a glycoprotein, a sugar, a lipid, an antigen, an antibody, a cytokine, a peptide, a neurotransmitter, a hormone, an ion, a messenger molecule, a nucleic acid, an engineered nucleic acid, a nucleic acid vector, a drug, a cell, a cell fragment, a cell organelle, a liposome, a pharmaceutical agent, a biological material, and/or a biological fraction internal and/or external to said reservoir.

9. (PREVIOUSLY PRESENTED) The device according to claim 1, wherein said at least one extensible finger is coupled to a source of two or more of a chemical, a chemical compound, a protein, a lipoprotein, a glycoprotein, a sugar, a lipid, an antigen, an antibody, a cytokine, a peptide, a neurotransmitter, a hormone, an ion, a messenger molecule, a nucleic acid, an engineered nucleic acid, a nucleic acid vector, a drug, a cell, a cell fragment, a cell organelle, a liposome, a pharmaceutical agent, a biological material, and/or a biological fraction internal and/or external to said reservoir.

10. (ORIGINAL) The device for perfusion management according to claim 1, further comprising an operative tool in communication with said extensible finger.

11. (ORIGINAL) The device for perfusion management according to claim 10, wherein said operative tool comprises a tool positioner.

12. (PREVIOUSLY PRESENTED) The device for perfusion management according to claim 10, wherein said operative tool comprises a device for ablating and/or degrading and/or liquefying a cell, a mass of cells, a tissue, and/or an assembly of biological materials exhibiting shear strength.

13. (ORIGINAL) The device for perfusion management according to claim 10, wherein said control circuitry is operative to guide said operative tool.

14. (PREVIOUSLY PRESENTED) The device for perfusion management according to claim 1, wherein said extensible finger includes a source of an electric charge and/or electromagnetic radiation coupled and/or carried by said extensible finger.

15. (PREVIOUSLY PRESENTED) The device for perfusion management according to claim 1, wherein the plurality of retractable segments are configured to articulate at joints of adjacent segments.

16. (PREVIOUSLY PRESENTED) The device for perfusion management according to claim 1, wherein said plurality of retractable segments are hollow.

17. (PREVIOUSLY PRESENTED) The device for perfusion management according to claim 1, wherein said extensible finger further comprises a device for fully or partially blocking and/or shunting a liquid flow.

18. (ORIGINAL) The device for perfusion management according to claim 1, further comprising a device for evacuating a target coupled to said extensible finger.

19. (PREVIOUSLY PRESENTED) The device for perfusion management according to claim 1, further comprising a device for cauterizing and/or sealing a cell, a mass of cells, a tissue, and/or an assembly of biological materials exhibiting shear strength carried by said extensible finger.

20. (ORIGINAL) The device for perfusion management according to claim 1, further comprising a fluid dispenser operative to provide a fluid at a controlled rate.

21. (ORIGINAL) The device for perfusion management according to claim 20, wherein said fluid dispenser is carried by said extensible finger.

22. (ORIGINAL) The device for perfusion management according to claim 1, wherein said extensible finger comprises a stent.

23. (ORIGINAL) The device for perfusion management according to claim 1, wherein said control circuitry is coupled to control said extensible finger.

24. (ORIGINAL) The device for perfusion management according to claim 1, wherein said control circuitry is operative to guide said extensible finger.

25. (PREVIOUSLY PRESENTED) The device for perfusion management according to claim 1, wherein said control circuitry comprises a processor, a feedback circuit, and/or a logic circuit.

26. (PREVIOUSLY PRESENTED) The device for perfusion management according to claim 1, wherein said control circuitry is a processor further comprising a stored software and/or firmware program cooperative with said processor.

27. (PREVIOUSLY PRESENTED) The device according to claim 1, wherein said device is of a size, a composition, a power dissipation level, and/or a shape configured for full or partial placement in vivo.

28. (ORIGINAL) The device for perfusion management according to claim 1, wherein said device is configured for implantation in an animal.

29. (ORIGINAL) The device for perfusion management according to claim 28, wherein said animal is human.

30. (PREVIOUSLY PRESENTED) The device for perfusion management according to claim 29, wherein said device is configured for placement in a selected location in said human corresponding to at least one physiological variable to be monitored and/or treated.

31. (PREVIOUSLY PRESENTED) The device for perfusion management according to claim 30, wherein said selected location is in a circulatory system, an aorta and/or a vena cava.

32. (PREVIOUSLY PRESENTED) The device for perfusion management according to claim 1, wherein said device is operative to provide and/or monitor a treatment and/or a response in a patient.

33. (PREVIOUSLY PRESENTED) The device for perfusion management according to claim 32, wherein said treatment comprises delivering a medicinal agent, a pharmaceutical agent, a therapeutic device and/or assembly to a location in said patient.

34. (ORIGINAL) The device for perfusion management according to claim 1, wherein said device communicates exterior to said patient.

35. (WITHDRAWN) A method of fabricating a perfusion management device, comprising:
forming a cavity for storing a receivable;
coupling a flexible conduit to said cavity, the conduit being configured to extend from said cavity to a target location in an animal's body; and
coupling said flexible conduit and said cavity to a monitoring system, said monitoring system including logic and/or software configured for directing said receivable from said cavity to said target location.

36. (WITHDRAWN) The method as in claim 35, comprising the step of configuring said device for implantation in proximity to said target location.

37. (WITHDRAWN) The method as in claim 35, comprising the step of configuring said device for providing and/or monitoring a treatment and/or a response in a patient.

38. (WITHDRAWN) The method for perfusion management according to claim 35, including coupling an imager, a pressure sensor, a temperature sensor, a chemical sensor, a gas sensor, an

electrolyte sensor, a flow sensor, a concentration sensor, a composition sensor, and/or a flow regulator to said monitoring system.

39. (WITHDRAWN) The method for perfusion management according to claim 35, further including coupling a pump, a motor, a vacuum, a siphon, and/or an evacuation device to said monitoring system.

40. (WITHDRAWN) The method for perfusion management according to claim 35, further including coupling an actuator, a tool positioner, an ablator, a cauterizer, and/or a sealer to said monitoring system.

41. (WITHDRAWN) The method for perfusion management according to claim 35, comprising the step of placing a source of a chemical, a chemical compound, a protein, a lipoprotein, a glycoprotein, a sugar, a lipid, an antigen, an antibody, a cytokine, a peptide, a neurotransmitter, a hormone, an ion, a messenger molecule, a nucleic acid, an engineered nucleic acid, a nucleic acid vector, a drug, a cell, a cell fragment, a cell organelle, a liposome, a pharmaceutical agent, a biological material, and/or a biological fraction internal and/or external to said cavity.

42. (WITHDRAWN) The method for perfusion management according to claim 35, comprising the step of placing a source of two or more of a chemical, a chemical compound, a protein, a lipoprotein, a glycoprotein, a sugar, a lipid, an antigen, an antibody, a cytokine, a peptide, a neurotransmitter, a hormone, an ion, a messenger molecule, a nucleic acid, an engineered nucleic acid, a nucleic acid vector, a drug, a cell, a cell fragment, a cell organelle, a liposome, a pharmaceutical agent, a biological material, and/or a biological fraction internal and/or external to said cavity.

43. (WITHDRAWN) The method for perfusion management according to claim 35, comprising the step of coupling and/or carrying a source of an electrical charge and/or electromagnetic radiation to said flexible conduit.

44. (WITHDRAWN) The method for perfusion management according to claim 35, wherein said monitoring system comprises a processor, a feedback circuit, and/or a logic circuit.

45. (WITHDRAWN) The method for perfusion management according to claim 35, wherein said monitoring system is a processor further comprising a stored software program cooperative with said processor.

46. (WITHDRAWN) The method for perfusion management according to claim 35, wherein said monitoring system communicates wirelessly.

47. (WITHDRAWN) A method for perfusion management, comprising:

storing a receivable in an implanted storage medium;

extending a flexible conduit between said storage medium and a target location; and

transmitting said receivable from said storage medium to said target location.

48. (WITHDRAWN) The method for perfusion management according to claim 47, comprising the step of gathering, processing, storing and/or transmitting data.

49. (WITHDRAWN) The method for perfusion management according to claim 47, further comprising the step of imaging, and/or detecting a level of pressure, temperature, chemical, gas, electrolyte, composition, concentration, and/or flow.

50. (WITHDRAWN) The method for perfusion management according to claim 47, comprising the step of delivering chemicals, chemical compounds, proteins, lipoproteins, glycoproteins, sugars, lipids, antigens, antibodies, cytokines, peptides, neurotransmitters, hormones, ions, messenger molecules, nucleic acids, engineered nucleic acids, nucleic acid vectors, drugs, cells, cell fragments, cell organelles, liposomes, pharmaceutical agents, biological materials, and/or biological fractions internal and/or external to said storage medium.

51. (WITHDRAWN) The method for perfusion management according to claim 47, comprising the step of performing one or more operations and/or actions.

52. (WITHDRAWN) The method for perfusion management according to claim 47, comprising the step of positioning tools.

53. (WITHDRAWN) The method for perfusion management according to claim 47, comprising the step of fully or partially blocking and/or shunting a liquid flow.

54. (WITHDRAWN) The method for perfusion management according to claim 47, comprising the step of ablating, degrading, and/or liquefying a cell, a mass of cells, a tissue, and/or an assembly of biological materials exhibiting shear strength.

55. (WITHDRAWN) The method for perfusion management according to claim 47, comprising the step of capturing a cell, a tissue, a fluid, a gel, a sample, a colloid, an emulsion, a debris, a contaminant, and/or a biological material.

56. (WITHDRAWN) The method for perfusion management according to claim 47, comprising the step of sampling a cell, a mass of cells, a tissue, and/or an assembly of biological materials exhibiting shear strength.

57. (WITHDRAWN) The method for perfusion management according to claim 47, comprising the step of cauterizing and/or sealing a cell, a mass of cells, a tissue, and/or an assembly of biological materials exhibiting shear strength.

58. (WITHDRAWN) The method for perfusion management according to claim 47, comprising the step of dispensing a fluid at a controlled rate.

59. (WITHDRAWN) The method for perfusion management according to claim 47, comprising the step of controlling and/or guiding said extensible finger.

60. (WITHDRAWN) The method for perfusion management according to claim 47, further comprising the step of placing said device fully or partially in vivo.

61. (WITHDRAWN) The method for perfusion management according to claim 47, comprising configuring said device for implantation in an animal.

62. (WITHDRAWN) The method for perfusion management according to claim 61, wherein said animal is human.

63. (WITHDRAWN) The method for perfusion management according to claim 62, further comprising configuring said device for placement in a selected location in said human.

64. (WITHDRAWN) The method for perfusion management according to claim 63, wherein said selected location is in a circulatory system, an aorta and/or in a vena cava.

65. (WITHDRAWN) The method for perfusion management according to claim 47, comprising the step of releasing an electric current and/or an electromagnetic radiation in proximity to a cell, a tissue, and/or an assembly of biological materials exhibiting shear strength.

66. (PREVIOUSLY PRESENTED) The device for perfusion management according to claim 1, wherein the plurality of retractable segments are configured to slidably collapse against adjacent segments and/or within an interior of adjacent segments of larger diameter.

67. (PREVIOUSLY PRESENTED) The device for perfusion management according to claim 1, wherein a length of the at least one extensible finger is controllably adjustable.

68. (PREVIOUSLY PRESENTED) The device for perfusion management according to claim 1, wherein articulation of the at least one extensible finger is controllably adjustable.

APPENDIX B. APPENDIX OF EVIDENCE (NOT APPLICABLE)

APPENDIX C. APPENDIX OF RELATED PROCEEDINGS (NOT APPLICABLE)